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COVID-19 VACCINATION IN THE UK AND IRELAND ETHICS IN PRACTICE

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Abstract

This working paper examines questions of values in relation to the COVID-19 vaccination programmes in the United Kingdom and Ireland. We first present a brief overview of developments in relation to COVID-19 vaccine development and rollout on a global basis. We then proceed with an examination of key ethical, policy and legal developments in these areas in the United Kingdom and Ireland, followed by the identification of commonalities and differences as between the two countries. In the final section, we consider the broader issue of values raised by the COVID-19 vaccination programmes in the UK and Ireland.

Keywords

COVID-19, COVID-19 Vaccination, COVID-19 Vaccination Programme, United Kingdom, Ireland, Ethics, Values, Law, Vaccine Regulation, Vaccine hesitancy, Vaccine inequalities

COVID-19 VACCINATION IN THE UK AND IRELAND ETHICS IN PRACTICE

PHELN WORKING PAPER NO. 1, JUNE 2021

**Clayton Ó Néill, Mary-Elizabeth Tumelty, Mary Donnelly, Anne-Maree Farrell,
Rhannon Frowde and Linda Pentony¹**

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COVID-19 VACCINATION IN THE UK AND IRELAND: ETHICS IN PRACTICE

PHELN WORKING PAPER NO. 1, JUNE 2021

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COVID-19 VACCINATION IN THE UK AND IRELAND: ETHICS IN PRACTICE

PHELN WORKING PAPER NO. 1, JUNE 2021

OVERVIEW

The purpose of this working paper (WP) is to explore questions of values in relation to the COVID-19 vaccination programmes in the United Kingdom (UK) and the Republic of Ireland (RoI). It considers three fundamental questions:

1. What values have, or should have, informed the COVID-19 vaccination programme?
2. How did we go about, or how should we have gone about, determining priority groups for COVID-19 vaccination?
3. What are some of the practical issues faced when implementing this type of vaccination programme?

The WP aims to provide a brief review of key policies, processes and practices that arose in relation to the design and implementation of COVID-19 vaccination programmes in the UK and the RoI. This will enable workshop participants to consider the three key questions noted above.

By way of background, we also provide short chronologies setting out key developments in relation to COVID-19 vaccination in the UK and RoI in **Appendices A** and **B** to this WP. As far as possible, we have endeavoured to ensure that the research and data presented in the WP is current as at **1 June 2021**.

We first present a brief overview of general developments in relation to COVID-19 vaccine development and rollout to date on both a local and global basis. We then proceed with an examination of key developments in these areas in the UK and the RoI, followed by identification of commonalities and differences as between the two. In the final section, we consider the broader issue of values raised by the COVID-19 vaccination programmes in the UK and the RoI.

PART I: COVID-19 VACCINE DEVELOPMENT AND ADMINISTRATION

On 31 December 2019, the World Health Organization (WHO) was notified of several cases of pneumonia of unknown origin in the city of Wuhan, China.² It soon became apparent that a new coronavirus was implicated, which would soon become known as SARS-CoV-2. Within a few weeks, cases of human-to-human transmission were increasing exponentially within and across borders. At the end of January 2020, the WHO declared a Public Health Emergency of International Concern (PHEIC) pursuant to the International Health Regulations.³ In March 2020, the WHO declared COVID-19 to be a global pandemic.⁴ As at the time of writing (8 June 2021), there are over 174 million cases of COVID-19 worldwide noted, and more than 3.7 million deaths from the disease recorded.

² World Health Organization, 'Pneumonia of Unknown Cause – China, 5 January 2020.' <https://www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/>

³ World Health Organization, *International Health Regulations 2005* (3rd edition, 2016). <https://www.who.int/ihr/publications/9789241580496/en/>

⁴ World Health Organization, 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19, 11 March 2020' <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>

Thus, the demand for a vaccine as a response to a global health challenge has never been more acute. As Calina et al. note '[t]he most favorable epidemic control scenario, which provides long-term protection against COVID-19 outbreak, is the development and distribution of an effective and safe vaccine.'⁵

In early 2020, over 100 vaccine projects were reported.⁶ As of 1 June 2021, there are a total of 287 candidate vaccines, with 102 in clinical phase and 185 in pre-clinical phase.⁷ Despite the unprecedented rapid development of multiple vaccines, demand continues to overtake supply.⁸ Recognising the significant healthcare inequalities which exist globally, and which have arguably been amplified by the pandemic, in May 2020, the WHO initiated a Solidarity Call to Action for COVID-19 with the goal of realising 'equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data.'⁹

Vaccination allocation and immunisation prioritisation are therefore key considerations. This section of the working paper (WP) considers the values which informed the rollout of the COVID-19 vaccination first in the UK and then in the Republic of Ireland.

PART II: COVID-19 VACCINATION IN THE UK

i. Introduction

In the UK, the first cases of COVID-19 were reported at the end of January, with the first case of a person contracting COVID-19 within the UK occurred at the end of February.¹⁰ Initially, the UK government and their scientific advisors appeared to support a 'herd immunity' approach to managing the disease,¹¹ but this had changed by mid-March, with pandemic modelling suggesting that following such an approach would soon overwhelm the National Health Service (NHS).¹² A series of lockdown measures were subsequently imposed to restrict people's movements, including the use of social distancing, working from home and only undertaking essential travel, leading to the cancellation of large social and sporting events.¹³ The UK Parliament subsequently adopted a piece of emergency legislation known as the Coronavirus Act 2020 to enable a UK-wide approach to manage lockdown measures, as well as a myriad of other issues that had arisen in the wake of the pandemic.¹⁴

⁵ D Calina and others, 'COVID-19 Vaccines: Ethical Framework Concerning Human Challenge Studies' (2020) 28(2) *Journal of Pharmaceutical Sciences* 807.

⁶ J Corum, K Sheikh, and C Zimmer, 'Different Approaches to a Coronavirus Vaccine', *The New York Times*, 20 May 2020.

⁷ World Health Organization, 'COVID-19 Tracker and Landscape' <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

⁸ For further discussion on global equitable access to COVID-19 vaccines please see, A McMahon, 'Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance' (2021) 47 *J Med Ethics* 142.

⁹ World Health Organization, 'Solidarity Call to Action', 29 May 2021 <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>

¹⁰ BBC News. 'Coronavirus: Latest Patient was First to Be Infected in UK', BBC News, 29 February 2020. <https://www.bbc.com/news/uk-51683428>

¹¹ D Conn and P Lewis, 'Documents Contradict UK Government Stance on Covid-19 'Herd Immunity'', *The Guardian*, 12 April 2020 <https://www.theguardian.com/world/2020/apr/12/documents-contradict-uk-government-stance-on-covid-19-herd-immunity>

¹² N Ferguson et al, Imperial College Covid-19 Response Team, 'Report 9: Impact of Non-Pharmaceutical Interventions (NPIs) to Reduce COVID-19 Mortality and Healthcare Demand' *Spiral* <https://doi.org/10.25561/77482>.

¹³ B Doherty, 'The Exit Strategy: How Countries Around the World are Preparing for Life after Covid-19' *The Guardian*, 18 April 2020. <https://www.theguardian.com/world/2020/apr/19/the-exit-strategy-how-countries-around-the-world-are-preparing-for-life-after-covid-19>

¹⁴ Coronavirus Act 2020, UK Public General Acts 2020, c 7.

ii. COVID-19 morbidity and mortality data

By way of background, there is a standardised approach to the reporting of deaths at the global level. This is set out under 'cause of death' in the WHO's International Classification of Diseases guidelines. Most routine mortality collected in the UK is based on what the WHO describes as the 'underlying cause of death'. This is defined as 'a) the disease or injury which initiated the train of morbid events leading directly to death, or b) the circumstances of the accident or violence which produced the fatal injury.'¹⁵ Death registration data is collected by the General Register Office in England & Wales. This is passed to the Office of National Statistics (ONS), which in turn publishes a range of mortality statistical data and is responsible for passing on a range of other government departments, as well as the WHO.

Notwithstanding this standardised approach, the COVID-19 pandemic has revealed that individual countries (including the UK) have taken their own approach to reporting causes of death in line with national guidelines. This may encompass the above classifications, but also be subject to further limitations imposed by an individual country. For example, the UK government and devolved nations record COVID-19 deaths as being based on a COVID-19 positive test within 28 days of death.¹⁶

Successive waves of the COVID-19 pandemic in the UK in the past year have resulted in significant morbidity and mortality in the UK from the disease. In January 2021, the UK reached the grim milestone of 100,000 Covid-19 related deaths in the UK, against a background where the country had the highest death rate per capita in the world for the pandemic at the time.¹⁷

As at 1 June 2021, there have been 4,490,438 cases of COVID-19 infection recorded in the UK, with over 127,782 deaths. These numbers are significant, and behind the sterility of the numerical data lie stories of separation, anguish and loss.

iii. COVID-19 vaccines and regulatory approval

A number of COVID-19 vaccines have been authorised by the UK regulator, the Medicines and Healthcare Regulatory Authority (MHRA). On 2 December 2020, the MHRA approved the Pfizer/BioNTech vaccine, which is an mRNA vaccine. At the time the vaccine was approved, the optimal approach to administration of this vaccine was considered to involve two injections being administered at least two days apart.¹⁸ The vaccine was to be stored in a freezer at -80 °C to -60°C and needed to be administered within six hours of thawing.¹⁹

The Pfizer/BioNTech vaccine was approved by the MHRA under Regulation 174 of the Human Medicine Regulations 2012 (2012 Regulations). In regulatory terms, the MHRA were able to authorise the rapid temporary approval of the vaccine, due to the serious public health concerns pertaining to the COVID-19 pandemic. The temporary authorisation allowed for the vaccine to be used by people over the age of 16 to prevent COVID-19, but it did not allow for a marketing authorisation.²⁰

¹⁵ World Health Organization, 'International Statistical Classification of Diseases and Related Health Problems' (ICD-10, 5th edn, WHO, 2016) <https://icd.who.int/browse10/2016/en>

¹⁶ UK Government, UK Coronavirus Dashboard. <https://coronavirus.data.gov.uk/>

¹⁷ BBC News, 'Covid Deaths: "Hard to Compute Sorrow" of 100,000 milestone – PM', 26 January 2021. <https://www.bbc.co.uk/news/uk-55814751>

¹⁸ Medicines and Healthcare Products Regulatory Agency (MHRA), 'Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 Vaccine', 4 June 2021. <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine>

¹⁹ Ibid.

²⁰ Medicines and Healthcare Products Regulatory Agency (MHRA), 'Decision: Information for UK Recipients on Pfizer/BioNTech COVID-19 Vaccine', 4 June 2021. <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine>

On 30 December 2020, the AstraZeneca (AZ) vaccine received regulatory approval by the MHRA for people over the age of 18 in the UK. The AZ vaccine was also approved under the 2012 Regulations. The AZ vaccine is a viral vector type vaccine and, therefore, differs from the mRNA approach adopted by Pfizer. It can be stored at 2°C-8°C in a standard fridge, making it much more accessible and straightforward in terms of delivery.²¹ It involves two injections, ideally to be administered between four and 12 weeks of receiving the first injection.

On 8 January 2020, the Moderna vaccine, another mRNA vaccine, was approved by the MHRA under the same 2012 Regulations. Like the Pfizer/BioNTech vaccine, the Moderna vaccine is another mRNA vaccine. The package leaflet gives the following explanation: The Moderna vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. It uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus.²² It is stored at -20°C and involves the administration of two doses for people in the UK over the age of 18 and, following consultation with healthcare professionals, the vaccine can be taken by pregnant people and those who are breastfeeding.²³

The MHRA recommended administering the Pfizer and AZ vaccines at different intervals to those initially advised by the pharmaceutical companies. A three-week gap between doses was originally scheduled for the Pfizer vaccine, but the UK decided to delay the gap between doses to ensure that as many people as possible received one vaccine and, thus, some protection from COVID-19.

Recently published data showed that this strategy may have proved effective. Public Health England and the University of Birmingham indicates that a 12 week gap between doses of the Pfizer vaccine 'increased the peak SARS-CoV-2 spike specific antibody response 3.5-fold compared to those who had the second vaccine at three weeks' and 'extending administration of the second Pfizer vaccine to 12 weeks potentially enhances and extends antibody immunity'.²⁴ There is also research to indicate that the 12 week gap between doses of the AZ vaccine has also had a positive effect on efficacy.²⁵

The Janssen (Johnson & Johnson) vaccine, which is a viral vector vaccine, was granted Conditional Marketing Authorisation (CMA) by the MHRA on 28 May 2021. Unlike the other COVID-19 vaccines, only one dose is required for this vaccine. It can be stored in the refrigerator between 2°C-8°C.

It was approved under the European Commission Decision Reliance Route.²⁶ The decision of European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) is relied upon. The decision of the CHMP is considered by the MHRA when deciding upon the quality, safety and effectiveness of the actual vaccine.²⁷ The decision of the MHRA has been endorsed by the Independent Commission on Human

²¹ Medicines and Healthcare Products Regulatory Agency (MHRA), 'Oxford University/AstraZeneca COVID-19 Vaccine Approval', 30 December 2020. <https://www.gov.uk/government/news/oxford-universityastrazeneca-covid-19-vaccine-approved>

²² 'Package Leaflet: Information for the User COVID-19 Vaccine Moderna Dispersion for Injection', revised 03/2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975784/PIL_Moderna_01.04.2021.pdf (accessed 14 May 2021).

²³ MHRA, 'Moderna Vaccine Becomes Third COVID-19 Vaccine Approved by UK Regulator', 08 January 2021. <https://www.gov.uk/government/news/moderna-vaccine-becomes-third-covid-19-vaccine-approved-by-uk-regulator>

²⁴ University of Birmingham, 'Delaying Second Pfizer Vaccine to 12 Weeks Significantly Increases Antibody Responses in Older People Finds Study', 14 May 2021. <https://www.birmingham.ac.uk/news/latest/2021/05/covid-pfizer-vaccination-interval-antibody-response.aspx>

²⁵ J Wise, 'Covid-19: New Data on Oxford AstraZeneca Vaccine Backs 12 week Dose Intervals' (2021) 372 BMJ n326. <https://www.bmj.com/content/372/bmj.n326>

²⁶ 'European Commission (EC) Decision Reliance Procedure' <https://www.gov.uk/guidance/european-commission-ec-decision-reliance-procedure>

²⁷ UK Government, 'Regulatory Approval of COVID-19 Vaccine Janssen', 28 May 2021. <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen>

Medicines. In NI, the Janssen vaccine was authorised under the CMA that was granted by the EMA on 11 March 2021.

iv. COVID-19 vaccination and priority groups

The Joint Committee on Vaccination and Immunisation (JCVI) is the UK's national scientific advisory body on vaccinations and their recommendations apply throughout the UK. On 30 December 2020, the JCVI approved an initial priority list for vaccination, which has been updated over time.²⁸ The list has been adopted by the UK and the devolved administrations. Details of the JCVI's current priority list for vaccination is set out in **Appendix D**.

v. COVID-19 vaccination and side effects

On 7 April 2021, the MHRA stated that the benefits of receiving the AZ vaccine (and protecting people from contracting COVID-19) outweighed the concerns pertaining to possible blood clots post inoculation.²⁹ The advice followed the temporary suspension of AZ vaccine in a number of European countries. On 28 April 2021, 242 blood clots had been reported to the MHRA following the administration of the AZ vaccine.³⁰ However, on 7 May 2021, the JCVI informed the UK government that, on a precautionary basis, the AZ vaccine ought not to be administered to anyone under the age of 40 if another vaccine were available and if no significant delay were caused.³¹

vi. COVID-19 vaccination programme rollout

On 20 December 2020, it was announced by Matt Hancock that there were plans to create vaccine centres in the UK. Thus, vaccines would be administered in designated centres as well as in hospitals, care homes and by General Practitioners (GPs).³²

On 08 December, a 90-year-old, Margaret Keenan, from Enniskillen in County Fermanagh, was the first patient outside of the clinical trials to receive the vaccine by the NHS. She received her second dose on 29 December 2020. On 14 December, the first Pfizer vaccines were administered in Scottish care homes. On 15 December, over 70 vaccination centres were opened in England. Care home vaccine centre locations opened on 16 December in England, where larger care homes were initially priorities. GPs started to provide vaccines later that week in December. In the UK, vaccines are also administered in community pharmacies. Patients in England started to receive the AZ vaccine on 04 January. The first four priority groups were given their vaccines during this initial stage, in line with the vaccination strategy. By 14 February, these priority groups had all been given their first dose. The Moderna vaccine was first administered on 7 April 2021 and the rollout began on 13 April. Around this time, new advice from the MHRA indicated that AZ should not be given to people under 30. This had an adverse impact on the vaccination rollout and new strategies were adopted. It was announced by Patricia Donnelly, Head of Covid-19 NI Vaccine Programme that, in areas where there was a low uptake of vaccinations in NI, pop-up centres would be opened.³³

By the end of April 2021, the vaccination rollout had opened up to those aged over 40 in England and those aged 30-34 in NI. On 07 May 2021, it was decided that those under 40 should not receive the AZ vaccine,

²⁸ Department of Health, 'COVID-19 Vaccination Programme Phased Plan', 8 March 2021 <https://www.health-ni.gov.uk/sites/default/files/publications/health/covid-vacc-prog-update-plan.pdf>

²⁹ 'UK Regulator Confirms that People Should Continue to Receive the COVID-19 Vaccine AstraZeneca', 7 April 2021. <https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca>

³⁰ Ibid.

³¹ Public Health England, 'JCVI Advises on COVID-19 Vaccine for People Aged Under 40', 7 May 2021. <https://www.gov.uk/government/news/jcvi-advises-on-covid-19-vaccine-for-people-aged-under-40>

³² BBC News, 'Covid-19: UK Setting Up for Vaccine Centres Ready for Rollout – Matt Hancock'. <https://www.bbc.com/news/uk-55021334>

³³ L Cullen, 'Covid-19: Pop Up Clinics to Target Areas of Vaccine Low Uptake', BBC News, 21 April 2021. <https://www.bbc.com/news/uk-northern-ireland-56837747>

again having an impact on the practicalities pertaining to the rollout. As things stand, in England, anyone aged 25 or over can book a vaccine, in Scotland, people over 30 can get a vaccine, while in Wales and NI, anyone over the age of 18 is eligible for a vaccine. This is at a time when the NHS is in a state of crisis. It is no overstatement to say that the vaccination programme has been a success story.

As at 1 June 2021, 39,585,665 first doses of COVID-19 vaccines have been administered in the UK, as well as 26,073,284 second doses.³⁴ Further details of the rates of COVID-19 vaccination on a UK-wide basis, as well as across the UK's four nations are set out in **Appendix E**.

vii. COVID-19 vaccination and consent issues

Unlike the RoI, consent has not presented itself as a key issue. This is largely due to the well-established framework that exists (such as the Mental Capacity Act 2005 in England and Wales).

viii. COVID-19 vaccine hesitancy

The issue of vaccine hesitancy is complex, and it is apparent that some of the hesitancy is imposed on people. It derives from a number of factors, some of which have been identified by the Nuffield Council on Bioethics and include benefits versus risks/uncertainty, mis-information (including information provided by influencers on social media), trust, values and practical considerations (e.g., childcare duties, availability, changing address, transport costs etc.).³⁵ The Nuffield Council has identified a number of potential strategies to reduce vaccine hesitancy. These include education and information campaigns, community engagement and incentivised and compulsory vaccination.³⁶ The primary lesson, however, is that, notwithstanding this hesitancy, the UK, in general, has a very high vaccine uptake, with, for example, 95% of the over 50s population taking the vaccine.³⁷

There are a number of surveys which indicate that people from some ethnic minorities are somewhat hesitant to take up their COVID-19 vaccine offer.³⁸ There is historical data to suggest that there is a lower vaccine uptake in areas that have a higher population of ethnic minority people.³⁹ According to Office of National Statistics, the main reason for vaccine hesitancy relates to perception about side effects and the potential impact of the vaccine on future health and wellbeing. According to Robertson et al, trust in the vaccine among black respondents is another significant reason for vaccine hesitancy.⁴⁰ Razai et al state that '[t]rust is eroded by systemic racism and discrimination, previous unethical healthcare research in black populations, under-representation of minorities in health research and vaccine trials, and negative experiences within a culturally insensitive healthcare system'.⁴¹ They also argue that barriers in terms of access exist (e.g., vaccine location and time). According to the Nuffield Council on Bioethics:

³⁴ Department of Health, 'NI Covid-19 Vaccinations Dashboard' <https://covid-19.hscni.net/ni-covid-19-vaccinations-dashboard/>

³⁵ MS Razai, T Osama and D G J McKechnie, 'COVID-19 Hesitancy Among Ethnic Minority Groups' (2021) 372n BMJ 513. <https://www.bmj.com/content/372/bmj.n513>

³⁶ Nuffield Council on Bioethics, 'Vaccine Access and Uptake' <https://www.nuffieldbioethics.org/publications/vaccine-access-and-uptake>

³⁷ BBC New, 'Covid: Vaccine Uptake Among Over 50s Hits 95% in England', BBC News, 22 April 2021. <https://www.bbc.com/news/health-56849874>

³⁸ Office of National Statistics, 'Coronavirus and the Social Impacts on Great Britain: 29 January 2021' <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/bulletins/coronavirusandthesocialimpactsongreatbritain/29january2021>; Royal Society for Public Health, 'New Poll Finds Ethnic Minority Groups Less Likely to Want Covid Vaccine' <https://www.rsph.org.uk/about-us/news/new-poll-finds-bame-groups-less-likely-to-want-covid-vaccine.html>

³⁹ Public Health England, 'Seasonal Influenza Vaccine Uptake in Children of Primary School Age', PHE, 2000-20; Razia et al (n 35).

⁴⁰ E Robertson et al, 'Predictors of COVID-19 Vaccine Hesitancy in the UK Household Longitudinal Study' (2021) 94, *Brain, Behaviour, and Immunity* 41-50.

⁴¹ Razai et al (n 35).

Vaccine hesitancy among people from some minority ethnic backgrounds during the roll out of COVID-19 vaccines has been linked to a lack of trust resulting from systemic racism and discrimination, historical abuses such as the Tuskegee syphilis study, underrepresentation of minorities in vaccine research, and negative experiences in the healthcare system.⁴²

Razai et al argue that, amongst some healthcare workers, there has been some vaccine hesitancy, and this 'is an area of concern because [their]... roles as trusted sources of health information, and because of their greater personal exposure to infections in a healthcare setting'.⁴³ There has also been some hesitancy on the parts of pregnant women as well as women who may wish to become pregnant (i.e. women of child bearing age) which may result from disinformation and the fact that pregnant women were not included in the clinical trials.⁴⁴

ix. COVID-19 vaccine passports and immunisation certificates

As the rollout of the UK COVID-19 vaccination programme has progressed, questions have been raised about whether individuals should hold vaccine passports or other forms of certification to show that they have been vaccinated. It has been suggested that this could be useful for the purposes of international travel, as well as entry into hospitality settings.⁴⁵ The UK government engaged in a public consulting on the feasibility of vaccine passports from 15 March to 29 March 2021.⁴⁶

On 17 May 2021, NHS England introduced a COVID passport on the NHS England app. This app contains NHS records and there is a section on vaccination status. In order to use the app, there is a need to be over the age of 13 and to be registered with a GP. As things stand, no such app exists elsewhere in the UK, but the UK government has indicated that it is working with the administrations in NI, Scotland and Wales in relation to creating similar apps.⁴⁷

In the UK, a traffic light system is in operation. If a country is in the red list, before travelling, passengers must take a COVID-19 test and book a hotel quarantine package, which includes another two tests. They must also fill-in in a passenger locator form. Once travellers arrive in the UK, they need to quarantine in the hotel and take two tests. Anyone travelling to a country on the amber list must complete a COVID-19 test as well as book and pay for day 2 and day 8 travel tests and complete a passenger locator form. On return to the UK, a COVID-19 test must be taken on days 2 and 8 and travellers to the country must quarantine at home (or where they are staying) for 10 days. If a country is on the green list, before travel, passengers need to take a COVID-19 test, book and pay for day 2 and day 8 travel tests and complete a passenger locator form. On return to the UK, a COVID-19 test must be taken on days 2 and 8, but there is no need to quarantine for 10 days.

More recently, the European Commission has recommended that people who have been vaccinated with a European Union (EU) approved vaccine at least two weeks before travelling should be permitted to travel

⁴² Nuffield Council on Bioethics (n 36).

⁴³ Razia et al (n 35).

⁴⁴ L Osborne-Crowley, "'There is a Lot of Distrust': Why Women in their 30s are Hesitant about the COVID Vaccine" *The Guardian*, 30 January 2021. <https://www.theguardian.com/society/2021/jan/31/there-is-a-lot-of-distrust-why-women-in-their-30s-are-hesitant-about-the-covid-vaccine>

⁴⁵ Institute for Government, Vaccine Passports, <https://www.instituteforgovernment.org.uk/explainers/vaccine-passports>

⁴⁶ UK Government, Cabinet Office, 'COVID-status Certificate Review – Call for Evidence – Now Closed, 15 March 2021. <https://www.gov.uk/government/consultations/covid-status-certification-review-call-for-evidence>

⁴⁷ BBC News, 'What is a Covid Passport and What are the Plans for the NHS App?' 12 May 2021. <https://www.bbc.com/news/explainers-55718553>

within the EU.⁴⁸ The Commission has also proposed that the EU certificate would include non-EU countries.⁴⁹ This would be evidenced by way of a 'digital green certificate'. At the time of writing, it is unclear as to exactly how well this will work in practice.

x. COVID-19 vaccine injury and redress

Under the Vaccine Damage Payments Act 1979, if an individual in the UK is left with severe disabilities following the administration of a vaccine, a tax-free payment of £120,000 may be provided. This is called the 'vaccine damage payment'.⁵⁰ Severe disability means that the person must be at least 60 % disabled, which includes both mental and physical disability. COVID-19 is now included in the list of diseases to which the Vaccine Damage Payments Act 1979 applies.⁵¹

PART III: COVID-19 VACCINATION IN THE REPUBLIC OF IRELAND

i. Introduction

In the RoI, the first cases of COVID-19 were reported at the end of February,⁵² with sadly, the first death of a person from COVID-19 in the RoI reported on 11th March 2020.⁵³ In contrast to the initial approach taken in the UK, a containment and preventionist approach was adopted in the RoI, with a series of lockdown measures imposed to restrict people's movements at an early stage in the pandemic.⁵⁴ These measures included the use of social distancing, the closure of childcare facilities, schools and higher education institutions, the implementation of remote working, and only undertaking essential travel, leading to the cancellation of large social and sporting events. The Irish Government subsequently adopted two pieces of emergency legislation: the Health (Preservation and Protection and Other Emergency Measures in the Public Interest) Act 2020 and the Emergency Measures in the Public Interest (Covid 19) Act 2020 to enable lockdown measures, as well as other issues which had arisen as a result of the pandemic.⁵⁵

ii. COVID-19 morbidity and mortality data

As previously noted, there is a standardised approach to the reporting of deaths at the global level. This is set out under 'cause of death' in the WHO's International Classification of Diseases guidelines. This is the approach followed in the RoI, and in this jurisdiction, morbidity and mortality data is collected by the Health Protection Surveillance Centre (HPSC).⁵⁶ In line with the WHO methodology, the definition of a COVID-19 death adopted by the HPSC provides that '[f]or surveillance purposes, COVID-19 deaths include deaths in all possible, probable and confirmed COVID-19 cases (as per the COVID-19 case definition and all should be notified, unless there is a clear alternative cause of death that cannot be related to COVID-19 (e.g. trauma). There should be no period of complete recovery from COVID-19 between the illness and death.

All COVID-19 deaths are notified regardless of the setting, including home, community and hospital settings. HPSC reports all deaths among these COVID-19 cases as outlined above and does not just confine the death reporting to those who die within 28 days of a positive test.' The guidance further provides that discharge

⁴⁸ BBC News, 'EU Unveils Plans for Overseas Tourists to Return', 3 May 2021. <https://www.bbc.com/news/world-europe-56970398>

⁴⁹ C Hymas, 'Holidays to Europe with Covid Vaccine Passports Get Green Light', *The Guardian*, 17 May 2021. <https://www.telegraph.co.uk/news/2021/05/17/holidays-europe-covid-vaccine-passport/>

⁵⁰ NI Direct, 'Vaccine Damage Payment' <https://www.nidirect.gov.uk/articles/vaccine-damage-payment-0>

⁵¹ Vaccine Damage Payments (Specified Disease) Order 2020.

⁵² [gov.ie](https://www.gov.ie) - Statement from the National Public Health Emergency Team - Saturday 29 February (www.gov.ie)

⁵³ [gov.ie](https://www.gov.ie) - Statement from the National Public Health Emergency Team - Wednesday 11 March (www.gov.ie)

⁵⁴ [gov.ie](https://www.gov.ie) - Statement from the National Public Health Emergency Team - Thursday 12 March (www.gov.ie)

⁵⁵ Health (Preservation and Protection and Other Emergency Measures in the Public Interest) Act 2020.

⁵⁶ The HPSC is a specialist agency within the HSE for the surveillance of all communicable diseases.

from ICU or hospital is not in itself evidence of recovery, rather, this is based on clinical assessment or the passing of a period of over three months since the initial diagnosis. As of 1 June 2021, 255,000 cases of COVID-19 infection and 4,941 deaths have been recorded in the RoI.

iii. COVID-19 vaccines and regulatory approval

For EU Member States, applications for the approval of COVID-19 vaccines are made centrally to the European Medicines Agency (EMA). Where the EMA is satisfied with the safety, quality, and effectiveness of a vaccine, it will make a recommendation to the European Commission to grant a conditional marketing authorisation. Once the European Commission makes a grant of approval, such is valid across all EU Member States, including Ireland.

To-date, four vaccines have been authorised by the EMA (two mRNA vaccines and two virus vector vaccines), with a number remaining under rolling review. On 21 December 2020, the EMA recommended the first COVID-19 vaccination for authorisation in the EU, developed by Pfizer/BioNTech.⁵⁷ Shortly thereafter, on 6 January 2021, the EMA recommended Moderna for authorisation in the EU.⁵⁸ On 29 January 2021, AZ is recommended for authorisation in the EU by the EMA,⁵⁹ and on 11 March 2021, the EMA recommended granting conditional authorisation for Johnson & Johnson's COVID-19 vaccine Janssen.⁶⁰

In the RoI, in the case of each vaccine, the National Immunisation Advisory Committee (NIAC) publish recommendations for use.⁶¹ Relevant materials are then prepared, and rollout plans are finalised. Some of the recommendations by NIAC will be discussed in more detail later in this WP, however, in summary, mRNA vaccines (Pfizer/BioNTech and Moderna) have been recommended for all age categories, whilst the virus vector vaccines (AZ and Janssen) were previously not recommended for those aged under 60.⁶² Additionally, NIAC recommended that pregnant people should be offered a mRNA COVID-19 vaccine.⁶³

iv. COVID-19 vaccination and priority groups

One of the most interesting ethical issues around vaccination policies is prioritisation for immunisation. With the overarching ethical goals of reduction of morbidity and mortality, countries worldwide have developed frameworks for the prioritisation of immunisation. This purpose of this section of the WP is to provide an overview of the approach adopted to vaccination policies and practices in the RoI.

In early June 2020, the Department of Health presented a draft proposal for the establishment of a vaccine taskforce to the National Public Health Emergency Team (NPHE).⁶⁴ This proposal recommended that a

⁵⁷ [EMA recommends first COVID-19 vaccine for authorisation in the EU | European Medicines Agency \(europa.eu\)](https://www.europa.eu/press-room/media/30612/en/ema-recommends-first-covid-19-vaccine-for-authorisation-in-the-eu)

⁵⁸ [EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU | European Medicines Agency \(europa.eu\)](https://www.europa.eu/press-room/media/30612/en/ema-recommends-covid-19-vaccine-moderna-for-authorisation-in-the-eu)

⁵⁹ [EMA recommends COVID-19 Vaccine AstraZeneca for authorisation in the EU | European Medicines Agency \(europa.eu\)](https://www.europa.eu/press-room/media/30612/en/ema-recommends-covid-19-vaccine-astrazeneca-for-authorisation-in-the-eu)

⁶⁰ [Fourth safe and effective vaccine against COVID-19 \(europa.eu\)](https://www.europa.eu/press-room/media/30612/en/ema-recommends-covid-19-vaccine-janssen-for-authorisation-in-the-eu)

⁶¹ The National Immunisation Advisory Committee was established in 1998 by the Royal College of Surgeons Ireland. It is an independent expert group with membership from immunisation from a range of healthcare professional bodies that provides evidence-based advice to the Chief Medical Officer and the Department of Health on vaccines, immunisation, and related health matters to inform health policies in Ireland. For further detail, see <https://www.rcpi.ie/policy-and-advocacy/national-immunisation-advisory-committee/>

⁶² Originally, NIAC recommended that the virus vector vaccines AstraZeneca and Janssen be provided to the 60-69 age category. This advice was subsequently revised on 29 April 2021, where it recommended that those aged 50 and over could receive this vaccine. More recently, NIAC have advised that people in their 40s can be given a choice and where they decline AstraZeneca and/or Janssen, they will be offered mRNA vaccines as supplies become available. See, [People in their 40s to be given choice of AstraZeneca or J&J vaccine \(irishtimes.com\)](https://www.irishtimes.com/news/health/people-in-their-40s-to-be-given-choice-of-astrazeneca-or-j-j-vaccine-1.4444444)

⁶³ [NIAC-Recommendations-re-vaccination-in-pregnancy-26.04.2021.pdf](https://www.niac.ie/media/1234567/NIAC-Recommendations-re-vaccination-in-pregnancy-26.04.2021.pdf)

⁶⁴ The National Public Health Emergency Team (NPHE), a body of approx. 30 health and science professionals, was established in January 2020 to provide advice on COVID-19, see Department of Health, National Public Health

COVID-19 Immunisation Strategy Group would identify priority groups for vaccination, amongst other objectives. On 18 June 2020, NPHET recommended that the Immunisation Strategy Group be established.⁶⁵ Parallel to this, the European Commission released the EU strategy for COVID-19 vaccines, with three core objectives: '1. Ensuring the quality, safety and efficacy of vaccines; 2. Securing timely access to vaccines for Member States and their population while leading the global solidarity effort; and 3. Ensuring equitable access for all in the EU to an affordable vaccine as early as possible.'⁶⁶

In the RoI, guidance on groups for immunisation prioritisation was developed and revised from November 2020 to April 2021 by the COVID-19 Immunisation Strategy Group and NIAC, with input from the Department of Health, the HSE, and the Health Information and Quality Authority (HIQA). On 2 November 2020, NIAC, at the request of the Department of Health, assisted the COVID-19 Immunisation Strategy Group, and presented their interim recommendations for identifying priority groups for vaccination,⁶⁷ noting the objective of the vaccination programme is to 'ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.'⁶⁸

Priority groups were identified 'according to the current and evolving understanding of the clinical, microbiological and epidemiological profile of COVID-19 internationally and in Ireland, with a focus on those at greatest risk from COVID-19.'⁶⁹ Additionally, it was noted that the foundations for the priority decisions made regarding the allocation of a COVID-19 vaccine are based on four core ethical principles: 1. Moral equality; 2. Minimisation of harm; 3. Fairness; and 4. Reciprocity.⁷⁰

A four-phase approach to the rollout of the vaccine was recommended, from highest to lowest priority.⁷¹ The criteria for prioritisation included: the risk of acquiring the disease; the risk of severe disease and death; the risk of a negative impact on society; and the risk of transmitting infection to others. The strategy for the allocation of COVID-19 vaccines was announced by the Minister for Health on 8 December 2020.⁷²

The priority list for vaccination has been revised. On 22 February 2021, NIAC published updated recommendations on priority groups for vaccination which advised the inclusion of additional medical conditions to the existing list of conditions associated with a risk of serious COVID-19 disease and death.⁷³ NIAC also advised that after the vaccination of those aged 70 and older, those aged 16-69 at very-high risk

Emergency Team – COVID-19 Meeting Note, 11 June 2020, <https://www.gov.ie/en/collection/691330-national-public-health-emergency-team-covid-19-coronavirus/>

⁶⁵ National Public Health Emergency Team (NPHET), Meeting Minutes, 18 June 2020.

<https://www.gov.ie/en/collection/691330-national-public-health-emergency-team-covid-19-coronavirus/>

⁶⁶ European Commission, EU Strategy for COVID-19 Vaccines (2020). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245&from=EN>

⁶⁷ [Priority-groups-SARS-CoV-2-vaccine-021120-.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf)

⁶⁸ <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf>

⁶⁹ Ibid.

⁷⁰ Ibid.

⁷¹ Phase one included frontline healthcare workers; essential workers e.g. gardai; those at greatest risk of severe illness and death and their caregivers; Phase two included teachers and others who are essential to education; those in essential jobs and who cannot avoid a high risk of exposure; adults aged 18-64 living or working in crowded accommodation; and adults aged 55-64 years; Phase 3 included young adults (18-34) due to increased levels of social contact; and those in industries important to the functioning of society and who are at moderately high levels of exposure; Phase 4 included adults aged 35-54 who did not have access to the vaccine in prior phases; and children.

⁷² [gov.ie - Minister for Health announces the allocation strategy for COVID-19 vaccines \(www.gov.ie\)](https://www.gov.ie/en/collection/691330-national-public-health-emergency-team-covid-19-coronavirus/)

⁷³ Conditions included cancer patients not covered under the previous cohort, cerebral palsy, and those with intellectual disabilities. [20210301-update-NIAC-Recommendations-for-COVID-19-Vaccine-Prioritisation.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf)

should be next to be vaccinated.⁷⁴ These recommendations are accepted by the Minister for Health on 23 February 2021.⁷⁵

More recently, on 29 March 2021, NIAC published a revised list for immunisation prioritisation, recommending that an 'operationally simple, age-based programme for those aged 16-64 in descending order is the most equitable and efficient way of continuing the vaccination rollout.'⁷⁶ This decision sparked considerable outcry by teachers' unions the Garda Representative Association (GRA).⁷⁷

v. COVID-19 vaccination and side effects

Whilst all medicines typically have side-effects, most debate in public discourse and the media has related to the safety of COVID-19 vaccines. Significant attention was given to the safety of the virus vector vaccines (AZ and Janssen) following reports of blood clots. In March 2021, an EMA safety committee commenced an investigation into a batch of the AZ vaccine after Austria and other Member States suspend use of the vaccine due to reports of blood clots.⁷⁸ Ultimately, however, the committee maintained the position that the benefits outweigh the risks and advised that the vaccine could continue to be administered.

By the 16 March 2021, however, 13 EU countries including the RoI paused the use of the AZ vaccine, despite the EMA's statement that the benefits outweighed the risks. Upon conclusion of the EMA's safety committee determination that the benefits of the vaccine continued to outweigh the risk of side effects, NIAC recommended that use of the AZ vaccine resume.⁷⁹ However, in subsequent guidance, the cohorts who were to receive this vaccine were limited.

As previously noted, in the RoI, guidance surrounding the issuance of vaccines to certain age groups was delivered by NIAC throughout the rollout of the vaccination programme. This guidance was particularly pertinent in the context of ongoing concerns in relation to blood clots. On 3rd February 2021, NIAC published recommendations for the use of AZ in Ireland, advising that 'any currently authorised COVID-19 vaccine can be given to adults of all ages, including those aged 70 and older'.⁸⁰ However, NIAC ultimately recommended that mRNA vaccines should be used for the over 70's 'where practicable and timely'.⁸¹

On 12 April 2021, NIAC also announced that the AZ vaccine 'is not recommended for those aged under 60 years, including those with medical conditions with very high or high risk of severe COVID-19 disease',⁸² and noted that 'mRNA vaccines are preferable for those aged under 50 years'.⁸³ Most recently, NIAC presented recommendations to the Chief Medical Officer, and ultimately recommended that people in their 40s were to be given a choice of vaccines i.e. people who decline to accept the AZ and Johnson & Johnson vaccines will be offered mRNA vaccines (Pfizer and Moderna) as supplies become available.⁸⁴

⁷⁴ Ibid.

⁷⁵ [gov.ie - Minister Donnelly announces update to Vaccine Allocation Strategy \(www.gov.ie\)](https://www.gov.ie/en/news/2021-03/minister-donnolly-announces-update-to-vaccine-allocation-strategy/)

⁷⁶ [NIAC-Recommendations-for-Vaccine-Prioritisation-29.03.2021-update-04.01.2021-1.pdf](https://www.niac.ie/media/29032021update040120211.pdf)

⁷⁷ See for example, E Loughlin and others, 'Teachers and Gardai "Shocked and Dismayed" at Changes to Vaccine Rollout Plan', *Irish Examiner*, 31 March 2021.

⁷⁸ [COVID-19 Vaccine AstraZeneca: PRAC preliminary view suggests no specific issue with batch used in Austria | European Medicines Agency \(europa.eu\)](https://www.european-council.europa.eu/media/402000/attachment/data/file/114000/COVID-19_Vaccine_AstraZeneca_PRAC_preliminary_view_suggests_no_specific_issue_with_batch_used_in_Austria.pdf)

⁷⁹ [NIAC-Recommendations-re-COVID-19-Vaccine-AstraZeneca-19.03.2021.pdf](https://www.niac.ie/media/29032021update040120211.pdf)

⁸⁰ [NIAC-Recommendations-to-CMO-Re-AZD.pdf](https://www.niac.ie/media/29032021update040120211.pdf)

⁸¹ Ibid.

⁸² National Immunisation Advisory Committee, Recommendations for the use of Vaxzevria COVID-19 Vaccine AstraZeneca (2021). <https://www.rcpi.ie/news/releases/national-immunisation-advisory-committee-niac-issues-revised-advice-on-the-use-of-the-astrazeneca-covid-19-vaccine/>

⁸³ <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf>

⁸⁴ [NIAC-Recommendations-re-COVID-19-Vaccination_29.04.2021.pdf](https://www.niac.ie/media/29032021update040120211.pdf)

vi. COVID-19 vaccination programme roll-out

The vaccine rollout programme began in late December 2020 / early January 2021. The effectiveness of a vaccine rollout strategy is dependent on a number of factors, including the administration of the vaccination. On 15 February 2021, the Minister for Health announced the location of COVID-19 vaccination centres around the country.⁸⁵ Whilst vaccines were also administered in healthcare settings and by GPs, these so-called mass vaccination centres were established with the aim of supporting ‘the vaccination of the general population in a safe and efficient manner.’⁸⁶

Similar to the approach taken in the UK, in Ireland, a COVID-19 vaccination may be only administered by certain healthcare professionals. An amendment to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 in December 2020 provides that registered nurses, pharmacists, paramedics, emergency medical technicians, and/or CORU registered Physiotherapist may administer the vaccine.⁸⁷ Following this, in February 2021, subsequent amendments were made to add registered optometrists and dentists to the list of healthcare professionals who may administer the COVID-19 vaccine.⁸⁸

A further point worthy of consideration is the tension between policy and practice. Whilst the immunisation prioritisation programme has considered and listed priority groups for vaccination, in practice, where excess vaccines exist, decisions on distribution ‘on the ground’ must be made. Controversies such as the Coombe Hospital, which involved the administration of 16 vaccine doses to family members of hospital employees, raised public consciousness on issues of fairness and equitable distribution.⁸⁹ A similar incident occurred subsequently where it was uncovered that the Beacon Hospital gave 20 ‘leftover’ doses of the vaccine to teachers in a private school.⁹⁰ These incidents highlight the importance of guidance for the distribution of supplemental vaccines, rather than reliance on individual discretion. This is important not only from the perspective of distributive justice, but also, public buy-in and support for the vaccination programme.⁹¹

The vaccination roll-out is still ongoing in the RoI.⁹² Further details of rates of first and second doses of COVID-19 vaccines across the UK’s four nations, as well as the RoI are set out in **Appendix E**. More recent statistics on the progress of the vaccination rollout in the RoI are currently unavailable following the cyber-attack on the Health Service Executive (HSE).

vii. COVID-19 vaccination and consent issues

An issue which required significant consideration in relation to the vaccination rollout in the RoI was that of consent, particularly in the context of adults with capacity difficulties. The Assisted Decision-Making (Capacity) Act 2015 (ADMCA) was signed by President Michael D. Higgins on 30 December 2015. The ADMCA will make substantial changes to the law in this area in the RoI,⁹³ however, the substantive elements of the legislation will not be commenced until 2022. As a result, the only legislative framework in place is the Lunacy

⁸⁵ [gov.ie - Minister for Health confirms locations for Ireland’s vaccination centres \(www.gov.ie\)](https://www.gov.ie/en/news/2021-02-15-minister-for-health-confirms-locations-for-ireland-s-vaccination-centres/)

⁸⁶ Ibid.

⁸⁷ Medicinal Products (Prescription and Control of Supply) (Amendment) (No 7) Regulations 2020 inserts Regulation 4F into the 2003 Regulations.

⁸⁸ S.I. No. 81 of 2021 Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021.

⁸⁹ S Carswell, ‘Coombe hospital chief “deeply regrets” that staff relatives were given Covid vaccines’ *The Irish Times*. 18 January 2021.

⁹⁰ E Moloney, ‘Beacon Vaccination of Teachers “A Slap in the Face to So Many” – Minister Simon Coveney’ *Irish Independent*, 28 March 2021.

⁹¹ Following these high-profile incidents, guidance was developed and published. See, [sequencing-of-covid-19-vaccination-of-frontline-healthcare-workers.pdf \(hse.ie\)](https://www.hse.ie/eng/healthcare_workers/covid19_vaccination_guidance.pdf)

⁹² For further information, see, <https://covid-19.geohive.ie/pages/vaccinations>

⁹³ For further discussion, see, M Donnelly, ‘The Assisted Decision-Making (Capacity) Act 2015: Implications for Healthcare Decision-Making’ (2016) 22(2) *Medico-Legal Journal of Ireland* 65.

Regulation (Ireland) Act 1871, which provides for admission to wardship.⁹⁴ Thus, the issue of consent in the context of the vaccine rollout was an important practical consideration.

The importance of this issue was highlighted by the President of the High Court, Ms. Justice Mary Irvine, who wrote to the Chief Medical Officer (CMO) on 11 December 2020 in relation to the administration of the COVID-19 vaccination to wards of court, and confirmed that there is no requirement to seek a Court Order for the administration of the vaccine.⁹⁵

On 24 December 2020, the Minister for Health signed S.I. No. 698 of 2020: Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. This introduces Regulation 10B which requires a vaccine administrator to forward the HSE information on the administration of the vaccine and the patient's personal details including confirmation that prior to the administration of the vaccine, consent was obtained or in the event where an individual lacked capacity to consent, 'the will and preferences of the person was established and the administration was for the benefit of the person'.⁹⁶

Additionally, the HSE Consent to Vaccination for COVID-19 Working Group was established in December 2020.⁹⁷ The HSE provided 'Guidance regarding Consent for COVID-19 Vaccination to public health staff and community health organisations on 12 February 2021, which outlines that where an individual has capacity to consent, 'they should make their own informed decision to consent or refuse consent to vaccination'.⁹⁸ Furthermore, where an individual lacks capacity, the guidance provides that a healthcare worker can 'decide on behalf of the person that they should receive vaccination and this should be based on the benefit to the person and knowledge of their will and preference'.⁹⁹

Additional guidance was published by the National Consent for COVID-19 Vaccination Working Group on 5 March 2021, which detailed the principles and processes of consent for vaccination for COVID-19.¹⁰⁰ Further guidance has been provided by the National Consent for COVID-19 Working Group in relation to adults with disabilities who attend a day service,¹⁰¹ and guidance for the vaccination of young people.¹⁰²

viii. COVID-19 vaccine hesitancy

One of the key challenges in a vaccination rollout of this scale is the issue of uptake. In the RI, the first Amárach Public Opinion survey, which specifically addresses vaccines, was published in January 2021. Of the 1,800 adults surveyed, 70% of participants said they would 'definitely' take a COVID-19 vaccine, with some 37% noting that they had concerns about receiving the vaccine.¹⁰³ Similarly, a more recent survey published on 10 May 2021, found of the 2,200 adults surveyed, 70% would 'definitely' take a COVID-19 vaccine when it is offered.¹⁰⁴ However, some hesitancy has been reported amongst pregnant people. One multi-national, cross-sectional survey reported that of 16,000 respondents (pregnant and breastfeeding individuals), 61%

⁹⁴ There are currently approximately 3,000 wards of court in the RoI.

⁹⁵ M Carolan, 'High Court President Writes to Holohan over Covid-19 Vaccine for Wards of Court' *The Irish Times*, 11 December 2020.

⁹⁶ Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020, Regulation 10B.

⁹⁷ The Group is chaired by Dr Siobhán Ní Bhriain, National Lead for Integrated Care. Membership includes an Operational Representative; Disability Representative; Mental Health Representative; GP representative; representatives from the National Office for Human Rights and Equality Policy; Chairs of the National Consent Advisory Group (Professor Shaun O'Keeffe and Professor Mary Donnelly).

⁹⁸ [guide4staffconsent.pdf \(hse.ie\)](https://www.hse.ie/eng/yourhealth/immunisation/covid19/guide4staffconsent.pdf)

⁹⁹ [guide4staffconsent.pdf \(hse.ie\)](https://www.hse.ie/eng/yourhealth/immunisation/covid19/guide4staffconsent.pdf)

¹⁰⁰ This document also provides detail on digital registration and consent. See, [Consent-Principles-5-March-2021 \(hse.ie\)](https://www.hse.ie/eng/yourhealth/immunisation/covid19/consent-principles-5-march-2021.pdf)

¹⁰¹ [process-for-provider-organisations-and-families-to-support-day-service-attendees-to-make-an-informed-decision-regarding-the-covid-19-vaccine.pdf \(hse.ie\)](https://www.hse.ie/eng/yourhealth/immunisation/covid19/process-for-provider-organisations-and-families-to-support-day-service-attendees-to-make-an-informed-decision-regarding-the-covid-19-vaccine.pdf)

¹⁰² [guidance-on-consent-for-vaccination-16-17-years.pdf \(hse.ie\)](https://www.hse.ie/eng/yourhealth/immunisation/covid19/guidance-on-consent-for-vaccination-16-17-years.pdf)

¹⁰³ <https://www.gov.ie/en/collection/6b4401-view-the-amarach-public-opinion-survey/>

¹⁰⁴ <https://assets.gov.ie/134643/939c1bce-31ca-4cf4-b9f8-0761da7a40d8.pdf>

would be willing to be vaccinated.¹⁰⁵ The traditional exclusion of this population from clinical trials has proven particularly problematic in the context of the pandemic from both the perspective of vaccine uptake amongst this cohort and from the perspective of improving maternal and fetal health.¹⁰⁶

A related consideration and challenge in the context of the vaccine rollout is that of the refusal of healthcare workers to be vaccinated. Vaccination of healthcare workers against COVID-19 is viewed as essential in ensuring the health and safety of the workforce, preventing transmission, and protecting healthcare capacity. As such, the refusal of healthcare workers to take the vaccine has raised interesting legal questions for employers such as the Health Service Executive (HSE).

Recognising the significant challenges posed by healthcare workers who refuse a COVID-19 vaccine, HIQA presented recommendations to NPHET for consideration on 8 April 2021.¹⁰⁷ HIQA recommended a policy based on an 'intervention ladder' and also suggested that consideration should be given to a number of solutions including redeployment.¹⁰⁸ These proposals for redeployment are currently under consideration by the HSE, following NPHET's endorsement of the approach advised by HIQA.

Despite the reported high rates of support for vaccination amongst the public, voices of dissent remain, as highlighted by the refusal by some healthcare workers to receive the vaccine and the high-profile case of *Medical Council v Waters*,¹⁰⁹ which involved the suspension of a GP for his refusal to administer the COVID-19 vaccine to his patients.

ix. COVID-19 vaccine passports and immunisation certificates

As part of the containment approach, travel restrictions have been implemented in the UK, and the RoI and other European countries, throughout the course of the pandemic. In the RoI, overseas travel was only permitted if considered essential, and associated penalties for non-essential overseas travel currently remain in place.¹¹⁰

With the vaccination rollout ongoing, focus has re-intensified on the possibility of overseas travel, including leisure trips. At a European level, the European Commission announced agreement on the issue of 'COVID passports' on 20th May 2021.¹¹¹ From 19th July 2021, the RoI plans to operate the EU Digital COVID Certificate (EUDCC) (previously called the Digital Green Certificate) for travel originating within the EU and EEA.¹¹² The EUDCC aims to open travel across the EU, with the EUDCC providing proof that an individual travelling has either been vaccinated against COVID-19; has received a negative test result; or has recovered from COVID-19. As such, under the system, fully vaccinated and recovered people holding certificates will be exempt from quarantines and other travel restrictions. The certificate will contain key information including name; date of birth; date of issue; relevant information about the vaccine / test / recovery; and a unique identifier number. Individual Member States will decide how the EUDCC will be implemented as part of national public health measures. Further details on the implementation of the EUDCC in the RoI are awaited.

¹⁰⁵ M Ceulemans et al., 'Vaccine Willingness and Impact of the COVID-19 Pandemic on Women's Perinatal Experiences and Practices – A Multinational, Cross-Sectional Study Covering the First Wave of the Pandemic' (2021) 18 *Int. J. Environ. Res. Public Health* 3367.

¹⁰⁶ See for example, D. D. Smith et al., 'Exclusion of pregnant women from clinical trials during the Coronavirus disease 2019 pandemic: A review of international registries' (2020) 37(8) *Am J Perinatol* 792; P Cullen, 'Half of pregnant women attending maternity hospital decline Covid-19 vaccine' (19 May 2021, *The Irish Times*).

¹⁰⁷ Advice to NPHET_HCPs who do not avail of vaccination (hiqa.ie)

¹⁰⁸ *Ibid.*

¹⁰⁹ [2021] IEHC 252.

¹¹⁰ Health Act 1947 (Sections 31A – Temporary Restrictions) (COVID-19) Regulations 2021.

¹¹¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2593

¹¹² <https://www.gov.ie/en/press-release/7894b-post-cabinet-statement-resilience-and-recovery-the-path-ahead/#international-travel>

In relation to travel outside the EU, the RoI will broadly follow the EU approach to non-essential travel i.e., an ‘emergency brake’ system will be applied to countries where a variant of concern arises.¹¹³ Thus, where a passenger has valid proof of vaccination and is travelling from a country which is not subject to an ‘emergency brake’, no travel-related testing or quarantine will be necessary. In contrast, where a passenger has proof of vaccination but is travelling from a country to which an ‘emergency brake’ has been applied, they will need to produce a negative PCR test taken no more than 72 hours before arrival, undergo self-quarantine, and undergo post-arrival testing. Where the passenger does not have proof of vaccination, they will be subject to the same requirements, with the addition of a required period of mandatory hotel quarantine. If an emergency brake is applied to a country, the Government advice will be to avoid travel to that country.

x. COVID-19 vaccine injury and redress

Whilst a detailed discussion on vaccine compensation programmes is outside the scope of this WP, it is important to note that in contrast to the UK,¹¹⁴ at present in the RoI, there is no State vaccine compensation scheme. This was an issue which was identified by an Expert Group appointed to review the law of torts and the current systems for the management of clinical negligence claims in 2018. In its report, the Expert Group observed that ‘there is a strong moral argument that the State, which actively encourages vaccination, should accept responsibility for those who suffer harm as a result.’¹¹⁵ The Group ultimately recommended that a vaccine compensation scheme be established ‘as a matter of urgency.’¹¹⁶

More recently, a vaccine injury compensation programme overview was prepared and presented to the Oireachtas,¹¹⁷ with a Dáil debate on the matter on 31 March 2021.¹¹⁸ However, further progress is yet to be made.

PART IV: COVID-19 AND THE ISLAND OF IRELAND

We also want to briefly highlight some key issues relevant to understanding the dimensions of managing the COVID-19 pandemic on the island of Ireland, which could be understood as single epidemiological unit in terms of the spread of the virus. Viewing the island in this way, however, presents a range of unique challenges in public health terms, given the island’s political history and in particular the ‘border question’.

From the UK’s point of view, NI is considered a devolved jurisdiction, comprising six counties in the North-East of the island of Ireland. While this jurisdiction was formally created in 1921, its constitutional status, including whether it should remain part of the UK or form part of a united Ireland, remains contested. During the period of what is commonly known as ‘The Troubles’, devolved government in NI was suspended on several occasions, with direct rule being imposed by the UK government during these periods.

In 1998, the Good Friday Agreement (or Belfast Agreement) was adopted, which provided for the re-establishment of devolved power-sharing institutions. The Agreement was based on the principle of consent in the context of the constitutional position of Northern Ireland and a right to self-determination subject to the consent of the majority in NI and RoI.¹¹⁹ Under the Good Friday Agreement, anyone born in NI can identify as an Irish citizen (and, therefore, hold an Irish/EU passport), as a British citizen (and, therefore, hold a UK

¹¹³ Ibid.

¹¹⁴ Vaccine Damage Act 1979.

¹¹⁵ Mr Justice Charles Meenan, Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims, January 2020, 7.

¹¹⁶ Ibid.

¹¹⁷ https://data.oireachtas.ie/ie/oireachtas/libraryResearch/2021/2021-04-20-I-rs-note-vaccine-injury-compensation-programmes-an-overview_en.pdf

¹¹⁸ Dail Deb 31 March 2021, vol 1005, col 5.

¹¹⁹ Good Friday/Belfast Agreement, 1998.

passport) or both. One of the unforeseen outcomes of this is potential problems associated with the EU Digital Covid Certificate.

A lack of clarity currently exists in relation to what the position will be of Irish (thus EU) citizens who live in NI and who were given vaccines under the NHS system. How will they be included on the EU Digital Covid Certificate? National authorities are currently responsible for issuing the certificate. It will exist as a paper certificate as a QR code on a mobile phone app. It is unclear, at this moment, how Irish citizens will be able to obtain the EU Digital Certificate. It is also unclear if the Irish government will be issuing certificates to Irish citizens who live in NI (which obviously includes a significant population of NI) or only those who reside in RoI.

Political tensions persist over the border between NI and RoI. In recent times, this has been exacerbated by the UK's decision to leave the EU, given that the North-South border on the island of Ireland has now become the sole land border between the UK and the EU. In the wake of Brexit, the NI Protocol has been a source of ongoing controversy.

It is also important to keep in mind, NI power-sharing institutions were only again restored in January 2020 following a period of direct rule in the period 2016-2019. It meant that the NI Executive was barely bedded in before it was forced to address the implications presented by the COVID-19 pandemic on a local basis, shared island basis and in terms of its relations with the other nations in the UK, more generally.

Health is a devolved matter and therefore it is primarily a matter for the NI Executive and the NI Assembly to make policy and law in this area.¹²⁰ Once the Coronavirus Act 2020 was in place, the NI Executive moved quickly to adopt its own laws to enable it to impose lockdown measures on a local basis.¹²¹ It has continued to adapt such measures through successive waves of the pandemic.

As between the NI and RoI jurisdictions on the island of Ireland, a number of nuanced similarities and differences between the approaches adopted in the jurisdictions have emerged. Underpinning these actions and, in some cases, inactions, lie values and ethics. These similarities and differences have emerged in light of the coming together of occasionally contrasting medical advice and political reasoning in the jurisdictions.

For the most part, these two factors have been positive influences on vaccine practices, but, occasionally, perhaps as a consequence of sometimes fraught political allegiances and sub-terranean tribalism, the alignment of medical advice, political action and subsequent decisions-making in respect of vaccines has not always been cohesive, coherent or fully reflective of joined-up thinking.

Notwithstanding the fact that NI and the Irish Republic are considered a single epidemiological unit and the fact that COVID-19 recognises no geographical borders, there was and is no particular consensus in respect of agreed vaccination actions across the island. Values that are held about nationality and whether that nationality is orange or green have, perhaps, led to decisions being made in line with practices in GB or RoI, according to political affiliation rather than medical necessity.

Similarities and differences between the NI (UK) and RoI:

- Unlike the RoI (via the European Medicines Agency), the UK regulator (MHRA) has not authorised the Johnson & Johnson/Janssen vaccine, which only requires the administration of one dose.
- Different time limits adopted in NI and RoI in respect of administration of first and second doses of the AZ and Pfizer vaccines.
- COVID-19 vaccination rates and vaccine hesitancy are different in NI and RoI.
- The issue of consent in relation to COVID-19 vaccination differs as between NI and RoI.

¹²⁰ Northern Ireland Act 1998, UK Public General Acts 1998, c. 47.

¹²¹ The Health Protection (Coronavirus, Restrictions) Regulations (Northern Ireland) 2020, NI SR 2020 No. 55.

- Vaccine injury redress differs as between the UK and RoI.
- Different approaches adopted in terms of prioritising age groups for vaccination, particularly with respect to the use of AZ and Janssen vaccines.

PART V: VALUES AND VARIATION: COVID-19 VACCINATION IN THE UK AND IRELAND

This WP addresses the issue of values as they pertain to practices surrounding immunisation and COVID-19. The ethical underpinning for the vaccination processes provided guidelines for societal conduct aimed at maximising the efficacy of immunisation approaches. Values are considered in this WP as, essentially, putting ethics into action.

Ethically appropriate mechanisms should be linked to the values, principles and ideals that are held by society. The interplay between ethics and values is not a semantic one. In the context of this WP, the value that is given to the age, employment, nationality, vulnerability and capacity or otherwise of the person is linked to the vaccination choices and opportunities that are provided.

Thus, the values that are held in respect of all these variables have resulted in people being treated differently because of their age, personal characteristics and medical history. This WP highlights the fact that a system of values lay behind and lies behind many of the decisions that have been made and are being made in respect of vaccination and COVID-19. We provide some examples to consider below.

Fairness

There is a very broad values-derived question about *fairness* and vaccination opportunities that needs to be addressed. In-depth consideration of this ethical issue is beyond the scope of this WP, but this issue is likely to be considered in much of the future international discourse surrounding sharing of resources in global medical emergencies and related inequity in practice. The issue of fairness is also, however, a local one. It still applies to the decisions made in respect of prioritisation of vaccines. Values are something that determine priorities that are adopted, and the current age-specific/vulnerability focused vaccination procedures adopted appear to give priority to older and more vulnerable people. Valuing people whose lives may have been devalued in the earliest stages of COVID-19, as evidenced by the high death rates in care homes, may be an appropriate course of action. However, the scientific community who are making the decisions about who is to be vaccinated are likely to be older. It may be significant (at least subliminally) that they have chosen to prioritise the vaccination of the cohort that best matches the values of the scientific community itself.

Within the general population in both NI and RoI, there is a commonly held view among many that some vaccines are 'better' than others. Someone who has a fear of getting a blood clot, for example, may wish to be given the Pfizer vaccine instead of the AZ vaccine. This creates a conundrum in relation to whether or not people should be allowed to choose which COVID-19 vaccine they receive. This gives rise to the ethical question as to how the current approach adopted in NI and RoI respects the autonomy of people.

Vulnerability

There has been much discussion about the way in which vaccine-eligibility have been prioritised. They have been focused on vulnerability (age and health status) as well as health/social care workers. There have been calls from differing professions, such as teachers, to receive prioritisation. This brings to bear the issue of 'value' and why one cohort of people should be prioritised over another. One may argue that someone working in a supermarket (on the so-called COVID-19 frontline) who is providing an essential service should be prioritised over someone who is not working, but fits into a higher position on the priority scale. The same

could, equally, be said about the Gardaí/police and many other work contexts. But if that is the case, where do we draw the line or what would the line look like? It would certainly be curvy or blurry.

Solidarity

To date, there has been a common drive towards vaccine and scientific evidence conclusively supports the vaccination of people. Academic and scientific voices that are vocal in their support of vaccines are heard loudly and consistently. These voices are valued in political, medical and mainstream media arenas. Less value is attached to those who are anti-vaccines: their voices are muted or derided or ignored or mocked, and they are certainly given little value. This workshop will look at the value that is ascribed to people who purport to hold anti-vaccine views. This aim of this approach is not to give voice to what may be irrational, pseudo-scientific theory, but this issue is highlighted in so far as it is possible that the muting of anti-vaccine proponents can give rise to a sub-culture of anti-vaxxers who find that their opinions are valued more in a cult-style milieu. This, ultimately, could have a negative impact on vaccination in the population and bears inclusion in our discourse.

Obviously, the key to future cohesion in the development of services to arrest the spread of COVID-19 will be the presence of increased cooperation and solidarity between the two jurisdictions. In such a scenario, actions would be taken out of medical and scientific necessity rather than along the intransigence of deeply embedded political lines. At a very human level, the people of NI and RoI are joined by the common purpose of the need to strive for health and wellbeing, which has been highlighted by COVID-19.

Public-private dimensions (market/economy)

The pandemic has had an undeniable impact on the global economy. The rollout of a vaccine, therefore, is an important aspect of planned economic recovery and has been described as ‘an exit strategy.’¹²² Whilst a detailed discussion on the balance between economic costs and public health considerations is outside the scope of this WP, it is prudent to briefly discuss this issue in the broader context of values and variation.

A key consideration for policy makers during the pandemic has been the balance between mitigating against the negative impact of lockdown measures on the economy and wider public health concerns. Globally, some countries have adopted more aggressive prevention and control strategies, whilst others have adopted ‘mitigating spread measures’.¹²³ Such actions have prevented morbidity. Whilst the vaccine rollout remains ongoing, in the UK and the RoI, businesses and industries previously closed by the pandemic have begun to re-open. Re-opening of the economy needs to involve a careful balance of public health and economic concerns, with many still awaiting a vaccine in the RoI. In the context of the vaccine rollout, particularly in the RoI, questions around the prioritisation of vaccination of workers in frontline positions e.g. supermarket workers; teachers; Gardaí, were raised.¹²⁴ However, ultimately an age-based approach to the rollout of the vaccine was adopted in the RoI and the UK.

More recently, in the UK, variants have brought additional challenges and localised lockdown measures have been considered. Similarly, in the RoI, a surge of cases in Limerick raised questions about the possibility of imposing localised lockdowns.¹²⁵ Thus, it appears that the balance between re-opening the economy whilst maximising public health continues to remain a key consideration.

¹²² R MacIntyre, ‘Navigating Post-Vaccine COVID-19 Futures in the Health and Economic Context’ (2021) *The Lancet Infectious Diseases*, published online March 18, 2021. [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00126-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00126-2/fulltext)

¹²³ C Seghieri et al., ‘Looking for the Right Balance Between Human and Economic Costs during COVID-19 Outbreak’ (2021) 33(1) *International Journal for Quality in Health Care* 155.

¹²⁴ M Wall, ‘Retail Workers Seek Early Access to Covid-19 Vaccine’, *The Irish Times*, 12 January 2021.

¹²⁵ A Moore et al., ‘Limerick Covid Outbreak: Cases Close Schools and Businesses but No Lockdown Decision Made’, *The Irish Examiner*, 4 June 2021.

Centre-periphery relation, urban-rural divide and border communities

The JCVI provides UK departments with advice in relation to immunisation. There are no representatives from NI on the JCVI. Does this GB-centred approach have an adverse impact upon the devolved nature of the Department of Health in NI, and does it reduce the autonomy of that Department and, indeed, of the Executive itself?

Human rights

Human rights are value-based instruments of thought of legal action and a vehicle for change. There are questions around human rights of those who have been vaccinated and those who never were vaccinated and who sadly died and whose right to life may have been breached by the failure to protect their life before the vaccinations were introduced.

Is the adoption of a vaccine passport for NI/Rola realistic, appropriate and ethical solution or would it result in a two-tiered, unfair and unethical system? The Council of Europe's Committee on Bioethics has indicated that such a passport would need to be carefully considered and to be human rights' compliant.¹²⁶ The Committee agrees with the Council of Europe's Secretary General, who stated that

combating the current pandemic depends, above all, on the increased efforts to produce and administer vaccines, with particular attention to people in vulnerable situations, so that restrictions to individual freedoms and constraints imposed can be progressively reviewed as the population acquires greater immunity, taking into account acquired scientific knowledge.¹²⁷

Under the European Convention on Human Rights (ECHR), freedoms can be curtailed as long as they are prescribed by law, proportionate and necessary. The Committee is particularly concerned about when a vaccine passport could be used to allow for 'exclusive access to services or to specific areas or as a requirement for entering a country.'¹²⁸ The issue of personal data that could be contained in a digital vaccination certificate could become an ethical minefield. According to the Committee, 'the processing of such data and information requires a particular high level of protection.'¹²⁹ The Committee also refers to the issues of 'scientific uncertainty' and the 'impact on social cohesion and solidarity.'¹³⁰ For example, the vaccine passport could cause, on one hand, a reason for people to be vaccinated or, on the other hand, reduce public confidence in vaccination programmes.¹³¹

Concluding comments

Sometimes values are not definitive, intransigent codes of reference for behaviour or belief. At other times they define the very psyche and personhood of the individual. Beyond the parameters of these two extremes lie gradients of importance that can be ascribed to values. Suffice to say that values form part of the vaccination decision-making process. The Nuffield Council on Bioethics states that social norms can be a significant player in decision-making. In a society where vaccination is regarded as 'normal' then it is more likely that a person will decide to be vaccinated.¹³² Religious or philosophical beliefs/values can have an

¹²⁶ Council of Europe Newsroom, 'Vaccine Passports: Protecting Human Rights and Personal Data', 4 May 2021/ <https://www.coe.int/en/web/portal/-/vaccine-passes-protecting-human-rights-personal-data>

¹²⁷ Committee on Bioethics, 'Statement on Human Rights Considerations Relevant to "Vaccine Pass" and Similar Documents', 4 May 2021. <https://rm.coe.int/dh-bio-2021-7-final-statement-vaccines-e/1680a259dd>

¹²⁸ Ibid 3.

¹²⁹ Ibid.

¹³⁰ Ibid 4.

¹³¹ Ibid.

¹³² Nuffield Council of Bioethics (n 36).

impact on whether or not someone is vaccinated.¹³³ Equally, '[i]deas about naturalness are sometimes invoked as a reason to reject vaccination'.¹³⁴ The challenge, into the future, is to ensure that a vibrant discourse around vaccination occurs that is founded upon the rigour of scientific fact. For this discourse to be beneficial, however, the values that people have as they pertain to this aspect of medical care need, at the very least, to be acknowledged.

¹³³ Ibid 4.

¹³⁴ Ibid.

APPENDIX A

CHRONOLOGY: COVID-19 VACCINATION IN THE UK

DATE	EVENT
2020	
Early April 2020	<ul style="list-style-type: none"> • The UK government launches the Vaccine Taskforce to combat COVID-19, leading efforts to develop, manufacture, and procure vaccines for the UK and globally.
Late April 2020	<ul style="list-style-type: none"> • The UK announces £42.5 million for clinical trials conducted by Imperial College and at the University of Oxford. • The UK begins the first human trials for COVID-19. • Human trials for the Oxford-AstraZeneca vaccine begin.
May 2020	<ul style="list-style-type: none"> • The UK promises another £84 million to help fund the mass production of the vaccine being trialled by the University of Oxford. • The UK has made provisional agreements for up to 100 million doses of the Oxford – AstraZeneca vaccine.
June 2020	<ul style="list-style-type: none"> • An announcement is released that the University of Oxford would be partnering with AstraZeneca to begin manufacturing the vaccine, despite not yet having received clinical approval. This deal is reached with a view to stockpile the vaccine in advance of its approval to facilitate and expedite deployment. • Imperial College begin human trials.
July 2020	<ul style="list-style-type: none"> • The UK signs a deal for 90 million doses of vaccines from Pfizer-BioNtech and Valneva. • The UK has made provisional deals for up to 60 million doses of the Sanofi-GlaxoSmithKline vaccine. • A major breakthrough is achieved in the sprint to find an effective vaccine, with trials suggesting the Oxford-AstraZeneca vaccine provides immunity.
August 2020	<ul style="list-style-type: none"> • The UK has made provisional deals for up to 60 million doses of the Novavax vaccine. • The UK has made provisional deals for up to 30 million doses of the Johnson & Johnson vaccine.
September 2020	<ul style="list-style-type: none"> • The UK has made provisional deals for up to 190 million doses of the Johnson & Johnson vaccine. • Novavax trials begin in the UK.
October 2020	<ul style="list-style-type: none"> • Changes to the Human Medicine Regulations to support the rollout of COVID-19 vaccines. • The JCVI issues advice on which groups should be prioritised for vaccination once a suitable vaccine candidate is approved. • UK announces plan to go ahead with ‘human challenge’ trials for a COVID vaccine, involving approx. 90 persons

Early November 2020	<ul style="list-style-type: none"> UK signed deal for 5m doses of Moderna vaccine, which announced 95% effectiveness. The UK has made provisional deals for up to 405 million doses of the Curevac vaccine. Pfizer and BioNTech announce that, after conducting the final efficacy analysis in their Phase 3 study, their vaccine candidate met all of the study's primary efficacy endpoints. Its analysis found that the vaccine is 95% effective.
Late November 2020	<ul style="list-style-type: none"> Matt Hancock announces plans to set up vaccine centres all throughout the UK. Boris Johnson states there will be no forced vaccination in UK. Health officials have warned that plans for mass testing in England threaten to be a distraction to other priorities, such as the rollout of a vaccine. New role of Parliamentary Under-Secretary of State for COVID-19 Vaccine Deployment set up. Nadhim Zahawi is the first to take office.
Early December 2020	<ul style="list-style-type: none"> UK approves Pfizer/BioNTech vaccine (Comirnaty). First batch (800,000) of Pfizer/BioNTech vaccines arrive in the UK on 3rd. COVID-19 vaccines added to VDPS, pursuant to the Vaccine Damage Payments (Specified Disease) Order 2020, SI 2020/1411 First patient receives the Pfizer/BioNTech vaccine on 8th. MHRA issued updated guidance of possible reactions and adverse interactions for the Pfizer/BioNTech vaccine.
Late December 2020	<ul style="list-style-type: none"> Vaccinations using the Pfizer/BioNTech vaccine begin in Scottish care homes More than 70 vaccination sites in operation in England. UK approves Oxford/AstraZeneca vaccine for use (AZD1222). JCVI Guidance on Priority Groups for COVID-19 Vaccination published. Vaccine delivery plan adjusted: JCVI delays the second dose of both vaccines. Focus on the initial dose.
2021	
Early January 2021	<ul style="list-style-type: none"> The first patient in England received the Oxford-AstraZeneca vaccine. Rollout of the Oxford/AstraZeneca vaccine begins in Northern Ireland on 04th. UK approves Moderna vaccine for use (MRNA-1273). NHS England announces that NHS health and social care staff will be given immediate priority on receiving the vaccine, with the majority vaccinated before February. The first vaccination strategy for Wales is published on 13th. The vaccination plan for Scotland is published by the Scottish Government on the 14th.
Late January 2021	<ul style="list-style-type: none"> AstraZeneca announces that it will prioritise its delivery of vaccines to the UK, over delivering vaccines to the EU, as it signed its contract with the UK first. Amid ongoing rows over vaccine shortfalls in the EU, the European Commission announced the introduction of control on vaccines made in the bloc, including Northern Ireland
February 2021	<ul style="list-style-type: none"> UK signed a deal for an extra 40 million doses of VLA2001 (Valneva) NHS England confirms that every older care home resident in England has been offered a COVID vaccine. England reaffirms they will not be introducing a vaccine passport. New study suggests Oxford/AstraZeneca offers minimal protection against the South African variant.

	<ul style="list-style-type: none"> England - All top four priority groups given their first dose on 14th, meeting the target of vaccinating 15 million before the 15th. UK government announces that it aims to offer all adults over 18 a vaccine before 31 July 2021. England - Vaccine priority list for adults under 50 announced.
Early March 2021	<ul style="list-style-type: none"> MHRA issues guidelines allowing fast-tracked approval of new versions of existing covid vaccines developed to fight variants. Health Minister Robin Swann rules out the idea of vaccine passports in Northern Ireland. Further dispute with EU over comment that the UK placed 'outright ban' on exports of vaccines produced in the UK. MHRA issues a statement: no evidence linking Oxford/AstraZeneca vaccine to increased risk of blood clots. WHO: no evidence linking the Oxford/AstraZeneca vaccine to blood clots Health officials in Northern Ireland announce that the use of the Oxford/AstraZeneca vaccine will continue, despite being suspended in the Irish Republic amid concerns about links to blood clots in Norway. Chief Medical Office for Scotland Gregor Smith affirms confidence in the Oxford/AstraZeneca vaccine after its use was paused by several European countries.
Late March 2021	<ul style="list-style-type: none"> England begins to vaccinate those aged 50 and over A letter from NHS England warns of a 'significant reduction' in the weekly supply of COVID vaccines – fewer AstraZeneca vaccinations will be available than expected. European Commission threaten to withhold vaccine exports to the UK (and any other non-EU countries) not supplying doses in a reciprocal manner. Scotland will get 500,000 fewer vaccine doses and Wales will receive 250,000 fewer vaccines over the next month due to a reduced supply of UK vaccines Health Minister Robin Swann says that all adults in Northern Ireland will receive their first vaccine by the end of July, in spite of an expected reduction in UK vaccines. Pam Kelly, Chief Constable of Gwent Police, calls for frontline police officers to be prioritised for the COVID vaccine. The Welsh Government in response says there is insufficient evidence to support vaccination by occupation A spokesperson for Prime Minister Boris Johnson declares that there are no surplus vaccines for the UK to share with other countries. JCVI: households where someone has a weakened immune systems should receive priority for vaccination. First Minister of Northern Ireland suggests once all adults in the UK are offered two doses then surplus may be offered to the Republic of Ireland.
Early April 2021	<ul style="list-style-type: none"> Wales is on target to become the first UK nation to offer all nine priority groups a first vaccine, and is on track to do so by Easter Sunday (4 April). MHRA finds 30 cases of rare blood clots in people after receiving the Oxford/AstraZeneca vaccine, but that benefits continue to outweigh the risks. MHRA confirms seven blood clot deaths among the 18 million vaccinated, unclear if these are a side effect. Wales meets target on 5th to offer vaccine to all nine priority groups. First dose of the Modern vaccine administered UK advises against giving the Oxford/Astrazeneca vaccine to under 30s. Adults under 30 are to be offered an alternative, following JCVI guidance of Oxford-AstraZeneca and blood clots.

	<ul style="list-style-type: none"> • Dr Richard Roberts, head of Wales's vaccination rollout, confirms one person in Wales has developed a blood clot following administration of the Oxford–AstraZeneca vaccine. • UK confirms everyone in the top nine priority groups has been offered their first COVID vaccine on 12th.
Late April 2021	<ul style="list-style-type: none"> • JCVI: changed advice for pregnant women. Recommended to receive the vaccine at the same time as others in their age group, and that Pfizer/Moderna are preferable. • Figures published by Public Health Wales indicate that vaccine uptake among black, Asian and other ethnic minority groups is 10% lower than in white communities, though the gap has narrowed slightly since February. • Public health officials in Scotland confirm that a digital scheme to enable people to prove their vaccine status is under development. • UK identifies 55 new cases of the Covid-19 variant first identified in India. • EU has launched a legal case against AstraZeneca – accused of not having a timely plan for the delivery of vaccines. • All over 40s in the UK will now be offered the vaccine.
Early May 2021	<ul style="list-style-type: none"> • The UK wide decision to offer adults under 40 an alternative to the Oxford AstraZeneca vaccine could delay Northern Ireland's vaccination programme. • The UK government confirms that from 17 May, those in England with both vaccines will be able to use the NHS app as a vaccine passport. • The gap between first and second vaccinations is narrowed to eight weeks for people in the top nine priority groups. • Concern over increased number of cases of the Indian variant, may be necessary to reimpose "economic and social" restrictions at a local or regional level and bring forward second doses in heavily impacted areas. • Research carried out by Public Health England suggests COVID vaccines have saved 11,700 lives and prevented 33,000 hospital admissions. •
Late May 2021	<ul style="list-style-type: none"> • Prime Minister Boris Johnson says there is "increasing confidence" COVID vaccines work against all strains of the virus, including the Indian variant. • Members of the public are urged to take part in a trial of a third COVID vaccine to determine its effectiveness against future strains of the virus. • Scotland – people travelling overseas will be able to access a vaccine certificate, either online or by request through post. • Failures in England's Test and Trace system are thought to be partly responsible for a surge in Indian variant COVID after eight local authorities did not have full access to the data for three weeks during April • Research carried out by Public Health England shows both the Pfizer and AstraZeneca vaccines are effective against the Indian COVID variant. • Janssen Vaccine approved for use in the UK • The World Health Organization changes its COVID variant naming policy, adopting Greek letters rather than areas of the world.
Early June 2021	<ul style="list-style-type: none"> • The UK records its first day with zero COVID-related deaths since March 2020; 3,165 new cases of the virus are announced. • EU Gateway (interconnection of national systems) goes live, as part of the EU's digital COVID-19 certificate programme. • Pfizer-BioNTech vaccine approved for 12 to 15-year olds by the MHRA, concluding that the benefits outweigh the risks.

ABBREVIATIONS	
2012 Regulations	Human Medicines Regulations 2012 ¹³⁵
BMA	British Medical Association ¹³⁶
EMA	European Medicines Agency ¹³⁷
JCVI	Joint Committee on Vaccination and Immunisation ¹³⁸
MHRA	Medicines and Healthcare products Regulatory Agency ¹³⁹
PHE	Public Health England
VDPS	Vaccine Damage Payments Scheme 1979 ¹⁴⁰

EXPLANATORY NOTES:

¹³⁵ These [Regulations](#) consolidate the law of the UK concerning medicinal products for human use, and were amended in October 2020 to facilitate authorisation and deployment of vaccinations.

¹³⁶ The [BMA](#) is the trade union and professional body for healthcare professionals in the UK.

¹³⁷ The [EMA](#) is an agency of the European Union responsible for the evaluation, approval and supervision of medical products. Until the end of December 2020, and as part of the transition period, vaccines could be licensed by the EMA and this authorisation would automatically be valid in the UK, however following this, such responsibilities have fallen to the remit of the MHRA.

¹³⁸ The [JCVI](#) is an independent advisory committee that advises the Government health departments in the four UK nations on immunisation, making recommendations concerning vaccine schedules and safety.

¹³⁹ The [MHRA](#) is an executive department of the Department of Health and Social Care that regulates medicines, medical devices and therapies in the UK. Any vaccine submitted for approval after the end of the transition period in January 2021 will be assessed directly by the MHRA.

¹⁴⁰ This provides for [vaccine damage payments](#), a one-off tax-free payment of £120,000 for persons severely disabled as a result of vaccination against certain diseases.

APPENDIX B

CHRONOLOGY: COVID-19 VACCINATION IN THE REPUBLIC OF IRELAND

DATE	EVENT
2020	
Late April 2020	<ul style="list-style-type: none"> Human trials for the Oxford/AstraZeneca vaccine begin.
May 2020	<ul style="list-style-type: none"> The WHO announces that there are 108 potential vaccines in development around the world, with 8 approved for clinical trials. Human trials for the Pfizer/BioNTech vaccine begin.
June 2020	<ul style="list-style-type: none"> The Inclusive Vaccine Alliance (comprising of France, Germany, Italy, and the Netherlands) reaches agreement with Oxford/AstraZeneca to supply up to 400 million doses of its COVID-19 vaccine with a view to make it available to other European countries. The European Commission Releases the EU Strategy for COVID-19 Vaccines announcing that it will ‘implement a joint approach going forward’ with the Inclusive Vaccine Alliance.
July 2020	<ul style="list-style-type: none"> The European Commission concludes exploratory talks with pharmaceutical company Sanofi-GSK to potentially purchase 300 million doses of their COVID-19 vaccine.
August 2020	<ul style="list-style-type: none"> The European Commission concludes exploratory talks with three pharmaceutical companies for the potential purchase of vaccines; Johnson & Johnson (up to 400 million doses), CureVac (initial purchase of 225 million doses), and Moderna (up to 160 million doses). The European Commission signs its first vaccine contract with Oxford/AstraZeneca to purchase an initial 300 million doses and an option of 100 million more. The EU pledges a €400 million contribution to support the COVID-19 Vaccine Global Access Facility (COVAX).
September 2020	<ul style="list-style-type: none"> The European Commission concludes exploratory talks with Pfizer/BioNTech to potentially purchase up to 300 million doses of their vaccine candidate. Oxford/AstraZeneca vaccine trial pauses globally as part of the standard review process after a participant experiences an unexplained illness. The European Commission signs its second vaccine contract with Sanofi-GSK for the purchase of up to 300 million doses.
October 2020	<ul style="list-style-type: none"> The European Medicine’s Agency (EMA) starts its first rolling review of a COVID-19 vaccine candidate (Oxford/AstraZeneca) and later starts a rolling review of the Pfizer/BioNTech vaccine. If successful, the vaccines will be evaluated for marketing authorisation. The European Commission signs its third vaccine contract with Johnson & Johnson for an initial purchase of 200 million doses and the possibility to purchase an additional 200 million. (This vaccine is one-dose only).
Early November 2020	<ul style="list-style-type: none"> The National Immunisation Advisory Committee (NIAC) presents interim recommendations identifying priority groups for a future COVID-19 vaccine. Pfizer/BioNTech announce that, after conducting the final efficacy analysis in their Phase 3 study, their vaccine candidate met all of the study’s primary efficacy endpoints. Its analysis found that the vaccine is 95% effective. The European Commission signs its fourth vaccine contract with Pfizer/BioNTech for an initial purchase of 200 million doses with an option to request an additional 100 million doses.

Late November 2020	<ul style="list-style-type: none"> • The European Commission signs its fifth vaccine contract with CureVac for an initial purchase of 225 million doses and an option to request an additional 180 million doses. • The EMA starts a rolling review of the Moderna vaccine candidate. Final results show the Moderna vaccine to be 94% effective. The European Commission signs its sixth vaccine contract with Moderna, for the purchase of an initial 80 million doses with an option to request a further 80 million doses. • The Immunisation Strategy Group is established, chaired by the Department of Health. • The High-Level Task Force, established by the Government, meets for the first time. The chair is Professor Brian MacCraith. The Task Force will work with the DOH and the HSE to have a national COVID-19 Vaccination Strategy and Implementation Plan prepared for the Government.
Early December 2020	<ul style="list-style-type: none"> • The Government approves an advance purchase agreement for 875,000 doses of the Moderna vaccine. • The EMA starts a rolling review of Janssen's vaccine candidate. • The Minister for Health announces the Allocation Strategy for COVID-19 vaccines. One week later the Minister announces the National COVID-19 Vaccination Strategy and an Implementation Plan prepared by the High-Level Task Force. • The president of the High Court, Ms. Justice Irvine, writes to the CMO concerning the administration of the COVID-19 vaccine to wards of court.
Late December 2020	<ul style="list-style-type: none"> • The European Commission concludes exploratory talks with Novavax to potentially purchase up to 200 million doses of their vaccine candidate. • The EMA recommends the Pfizer/BioNTech vaccine as the first COVID-19 vaccine for authorisation in the EU. The European Commission authorises the vaccine for use following this. • NIAC provides recommendations to the DOH for the COVID-19 vaccination rollout. • The Minister for Health signs S.I. No. 698 of 2020: Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 authorising COVID-19 vaccines to be administered in the State. • The first batch of Pfizer/BioNTech vaccines arrive in the Republic (9,950 doses). • The first dose of the vaccine is administered on the 29th.
2021	
Early January 2021	<ul style="list-style-type: none"> • The EMA recommends the Moderna vaccine for authorisation in the EU, which is then authorised for use by the European Commission. • The Minister for Health announces that 875,000 doses of the Moderna vaccine have been ordered by the Government and 3.3 million doses of the Pfizer/BioNTech vaccine have been ordered. • The COVID-19 vaccine rollout begins in privately-owned and voluntary nursing homes. The Minister for Health also announces and acceleration of the vaccination programme, using its one-week buffer to speed up vaccinations. • The European Commission proposes to purchase up to 300 million additional doses of the Pfizer/BioNTech vaccine, with 75 million doses available by the second quarter of 2021. • The European Commission concludes exploratory talks with Valneva with a view to purchasing up to 60 million doses of their vaccine candidate. • The first shipment of Moderna vaccines arrive in Ireland (3,600 doses).
Late January 2021	<ul style="list-style-type: none"> • Approximately 1,800 medical staff are vaccinated in centres nationwide; almost all GPs in the State have received their first dose of the Moderna vaccine. • The Government requests early deliveries of the Oxford/AstraZeneca vaccine, subject to EU approval. • It is revealed that the Coombe Women & Infants University Hospital in Dublin gave 16 excess vaccine doses to family members of hospital employees. The HSE is asked to compile a report into the administration of 'spare' vaccines to non-frontline staff following the hospital controversies.

	<ul style="list-style-type: none"> The European Commission adopts a Communication calling on Member States to speed up the roll out of vaccines across the EU. The EMA recommends COVID-19 vaccine Oxford/AstraZeneca for authorisation in the EU. Ireland is expected to receive 300,000 fewer doses of the Oxford/AstraZeneca vaccine as a result of a shortfall in deliveries to the EU.
Early February 2021	<ul style="list-style-type: none"> The EMA starts a rolling review of Novavax's COVID-19 vaccine candidate. The HSE's Consent for COVID-19 Vaccination Working Group publishes a Guidance Note on 'Supporting the consent process in those who lack capacity and are anxious/or refusing vaccination' The first shipment of Oxford/AstraZeneca vaccines (21,600 doses) arrives in Ireland. New study suggests Oxford/AstraZeneca vaccine offers minimal protection against the South African COVID-19 variant. The High Court rules that the HSE was correct not to seek court orders to have the COVID-19 vaccine administered to a ward of court against her wishes. The HSE circulates a 'Guidance regarding Consent for COVID 19 Vaccination'. The EMA starts a rolling review of CureVac's COVID-19 vaccine candidate.
Late February 2021	<ul style="list-style-type: none"> The Minister for Health announces the locations of 37 COVID-19 vaccination centres around the country. Community vaccination of Cohort 3 (over 70s) begins, with those 85 years and older the first to be vaccinated at selected GP practices. The European Commission approves a second contract with Moderna, for an additional purchase of 300 million doses until 2022. NIAC publishes updated recommendations on Priority Groups for vaccinations, adding new medical conditions to the list and advising that 16-69 year olds at very high risk should be vaccinated next after the over 70s. The Minister for Health signs S.I. No. 81. Of 2021 Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 which adds registered optometrists and registered dentists to the list of vaccine administrators. The Government publishes a revised plan for living with and reducing the spread of COVID-19, 'Resilience and Recovery 2021 Plan: The Path Ahead'.
Early March 2021	<ul style="list-style-type: none"> The National Consent for COVID-19 Vaccination Working Group publish the 'Consent for vaccination for COVID-19: Guiding Principles'. More than half a million vaccines have been administered in the State. Vaccination of Cohort 4 (those aged 16-69 at very high risk) begins. The European Commission orders four million more doses of the Pfizer/BioNTech vaccine for quick delivery to tackle hotspots. The EMA begins reviewing the Oxford/AstraZeneca vaccine after Austrian authorities and other Member States suspend use of the vaccine following reports of blood clots. The Johnson & Johnson's vaccine Janssen is the fourth to be authorised in the EU. NIAC recommends the temporary deferral of the Oxford/AstraZeneca vaccine. Some 30,000 people due to receive it will have their vaccination rescheduled. WHO say there is no evidence linking the Oxford/AstraZeneca vaccine to blood clots.
Late March 2021	<ul style="list-style-type: none"> The European Commission proposes to create a Digital Green Certificate to facilitate safe free movement inside the EU during the COVID-19 pandemic. The EMA concludes its preliminary review of blood clots in people vaccinated with the Oxford/AstraZeneca vaccine and confirms that the benefits continue to outweigh the risk of side effects. NIAC recommends resuming the rollout. It is revealed that 20 excess doses from the Beacon Hospital's vaccine programme, were used to vaccinate teachers and staff from a school near Bray. The Minister for Health calls for the HSE to suspend vaccine operations at the hospital following the controversy. The European Commission announce that Oxford/AstraZeneca must deliver vaccines to the EU before it can export doses elsewhere in the world.

	<ul style="list-style-type: none"> NIAC recommends that the vaccine rollout be changed to an age-based system following the current priority groups being vaccinated. There is controversy among teachers' associations and Gardaí representatives following the change to the vaccine rollout.
Early April 2021	<ul style="list-style-type: none"> Gardaí and teachers demand that the Government ensure they are vaccinated earlier. The EMA concludes that unusual blood clots with low blood platelets should be listed as very rare side effects of the Oxford/AstraZeneca vaccine. One millionth vaccine dose is administered. The HPRA investigates the first ever case of a blood clot associated with the Oxford/AstraZeneca vaccine. The EMA starts a review to assess reports of 'unusual blood clots' in people who received the Johnson & Johnson Janssen vaccine in the US. NIAC announces that the Oxford/AstraZeneca vaccine is not recommended for those aged under 60 years, including those at very high or high risk. Johnson & Johnson announce that they will proactively delay the rollout of the Janssen vaccine in Europe after reports of blood clots.
Late April 2021	<ul style="list-style-type: none"> The HSE's online portal for vaccination opens for those aged 65-69. This begins the vaccination of Cohort 5, people aged 60-69. The EMA concludes that a warning about unusual blood clots with low blood platelets should be added to the Janssen vaccine product information. NIAC publishes recommendations for COVID-19 vaccination in pregnancy. The EU launches legal action against Oxford/AstraZeneca 'for not respecting its contract for the supply of Covid-19 vaccines and for not having a "reliable" plan to ensure timely deliveries.' NIAC publishes updated recommendations for COVID-19 vaccination after laboratory confirmed infection and new recommendations that mRNA vaccines are preferable for those aged 50 and younger.
Early May 2021	<ul style="list-style-type: none"> The EMA starts evaluating the use the Pfizer/BioNTech vaccine in young people aged 12 to 15. Registration on the HSE's online vaccination portal begins for Cohort 9, people aged 50-59. The HSE considers proposals for the redployment of HSE staff who refuse Covid-19 vaccines. The first doses of the Johnson & Johnson Janssen vaccine are administered. The HSE suffers a major ransomware cyberattack that causes all of its IT systems to be shut down, but the vaccine registration portal is restored later the same evening.
Late May 2021	<ul style="list-style-type: none"> Following NIAC recommendations, people in their 40s are to be given choice of Oxford/AstraZeneca or Janssen vaccines. Registration on the HSE's online vaccination portal begins for people aged 45-49. The European Commission signs a third contract with Pfizer/BioNTech which reserves an additional 1.8 billion doses between the end of 2021 to 2023. The European Parliament and Council reach agreement on the Commission's proposal for a Digital COVID Certificate. The Pfizer/BioNTech vaccine is the first COVID-19 vaccine approved for children aged 12 to 15 in the EU.
1 st June 2021	<ul style="list-style-type: none"> EU Gateway (interconnection of national systems) goes live, as part of the EU's Digital COVID-19 Certificate programme.

ABBREVIATIONS	
CMO	Chief Medical Officer (Department of Health)
DOH	Department of Health
EMA	European Medicines Agency
HPRA	Health Products Regulatory Authority ^[1]
HSE	Health Service Executive ^[2]
NIAC	National Immunisation Advisory Committee ^[3]
SI	Statutory Instrument

EXPLANATORY NOTES

^[1] HPRA: The Health Products Regulatory Authority is a state agency to protect and enhance public and animal health by regulating medicines, medical devices, and other health products, and monitoring the safety of cosmetics. (<https://www.hpra.ie/>)

^[2] HSE: The Health Service Executive is the publicly funded healthcare system in the Republic of Ireland, responsible for the provision of health and personal social services. (<https://www.hse.ie/eng/>)

^[3] NIAC: The National Immunisation Advisory Committee was established in 1998 by the Royal College of Surgeons Ireland. It is an independent expert group with membership from immunisation from a range of healthcare professional bodies that provides evidence-based advice to the Chief Medical Officer and the Department of Health on vaccines, immunisation, and related health matters to inform health policies in Ireland. (<https://www.rcpi.ie/policy-and-advocacy/national-immunisation-advisory-committee/>)

APPENDIX C

PRIORITY GROUPS AND COVID-19 VACCINATION IN THE UK

Please note: The Joint Committee on Vaccination and Immunisation (JCVI) identified priority groups for COVID-19 vaccination in the UK on 30 December 2020

<https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020>

The UK's devolved administrations have implemented their own COVID-19 vaccination rollout programmes on a phased basis. For example: Wales, COVID-19 Vaccine Priority Groups <https://gov.wales/covid-19-vaccine-priority-groups>; Scotland, COVID-19 Vaccination Programme Priority List <https://www.gov.scot/publications/foi-202100144309/>; and Northern Ireland, COVID-19 Vaccination Programme Phased Plan <http://www.health-ni.gov.uk/publications/covid-19-vaccination-programme-phased-plan>, which is set out below by way of example.

Priority	Risk group	Phase	Timeline
1	Older adults resident in a care home and care home workers (12k residents and 16K staff)	Phase 1	Dec/Jan 2021
2	All those 80 years of age and over (<72K) and health and social care (70K) and domestically care workers (<25K)	Phase 1	Dec/Jan 2021
3	All those 75 years of age not already vaccinated (<62K)	Phase 2	Jan/Feb 2021
4	All those 70 years of age not already vaccinated (<81K) and extremely clinically vulnerable (95K) and Carers.	Phase 2	Jan/Feb 2021
5	All those 65 years of age not already vaccinated (<90K)	Phase 2	Jan/Feb 2021
6	All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality + the Carers	Phase 2	Jan/Feb 2021
7	All those 60+ years of age not already vaccinated (<106K)	Phase 3	Mar/April 2021
8	All those 55+ years of age not already vaccinated (<125K)	Phase 3	Mar/April 2021
9	All those 50+ years of age not already vaccinated (<132K)	Phase 3	Mar/April 2021
10	All those 40+ years of age not already vaccinated (<242k)	Phase 4	Mar/April 2021
11	All those 30+ years of age not already vaccinated (<251k)	Phase 4	Apr/May 2021
12	All those 18+ years of age not already vaccinated (<282k)	Phase 4	Apr/May 2021
13	Autumn/ Winter booster programme 2021	Phase 5	Winter 2021 onwards

APPENDIX D**PRIORITY GROUPS AND COVID-19 VACCINATION IN the REPUBLIC of IRELAND**

Priority	Priority group	Rationale	Phases¹⁴¹	Roll-out
1	People aged ≥65 years who are residents of long-term care facilities (and healthcare workers/staff of these facilities)	At greatest risk of severe illness and death.	Initial Roll-Out	29 Dec 2020
2	Frontline healthcare workers (in direct patient contact roles, including vaccinators, or who risk exposure to bodily fluids or aerosols and those providing services essential to the vaccination programme)	At very high or high risk of exposure and/or transmission.	Initial Roll-Out	7 Jan 2021
3	People aged 70 and older in the following order: ≥85 years; 80-84 years; 75-79 years; and 70-74 years	At higher risk of hospitalisation and death.	Initial Roll-Out	15 Feb 2021
4	People aged 16-69 with a medical condition that puts them at very high risk of severe COVID-19 disease and death.	At similar very high risk of hospitalisation & death as those aged 70-74.	Initial Roll-Out	8 Mar 2021
5	All people aged 60-69 (including those at high risk) ¹⁴² (65-69 ages initially, with ages 60-64 initiating on 23 rd April)	At high-risk of hospitalisation & death	Initial Roll-Out	15 Apr 2021
6	Other people aged 65-69 and key workers essential to the vaccine programme ¹⁴³	At high-risk of hospitalisation & death.	Initial Roll-Out	No data
7	People aged 16-59 years with medical conditions. ¹⁴⁴	At high risk of severe COVID-19 disease	Initial Roll-Out	No data
8	Residents of long-term care facilities aged 16-64 ¹⁴⁵	High risk of transmission	Initial Roll-Out	No data
9	People aged 50-59 years ¹⁴⁶		Mass Ramp-Up	No data

EXPLANATORY NOTES

¹⁴¹ The three phases were outlined in the National COVID-19 Vaccination Programme: Strategy. The three phases are (i) Initial Roll-Out (for limited number of doses); (ii) Mass Ramp-up; (iii) Open Access. The population to be vaccinated for each of these phases would be determined 'per Government-approved population sequencing'. The Initial Roll-Out phase vaccination sites were listed as long-term care facilities and large-scale healthcare sites which coincides with the focus on the highest priority groups identified being in these settings. The latter phases would initiate following large numbers of doses being available with primarily have mass vaccination centres and GPs and pharmacies used as vaccination sites.

¹⁴² Under the original vaccine allocation strategy this cohort was 'people aged 65-69 whose underlying condition puts them at a high risk of severe COVID-19 disease and death' but following the change to an age-based system, the cohort was amended.

¹⁴³ This group is no longer an active cohort as it was intended to be vaccinated simultaneously with cohort 5 and the two cohorts merged when the age-based system was introduced.

¹⁴⁴ Under the original vaccine allocation strategy this cohort was 'people aged 16-64 who have an underlying condition that puts them at high risk of severe disease and death' but changed following the introduction to an age-based system.

¹⁴⁵ This is no longer an active cohort due to the changes to an age-based system, people in this cohort are now being vaccinated according to age.

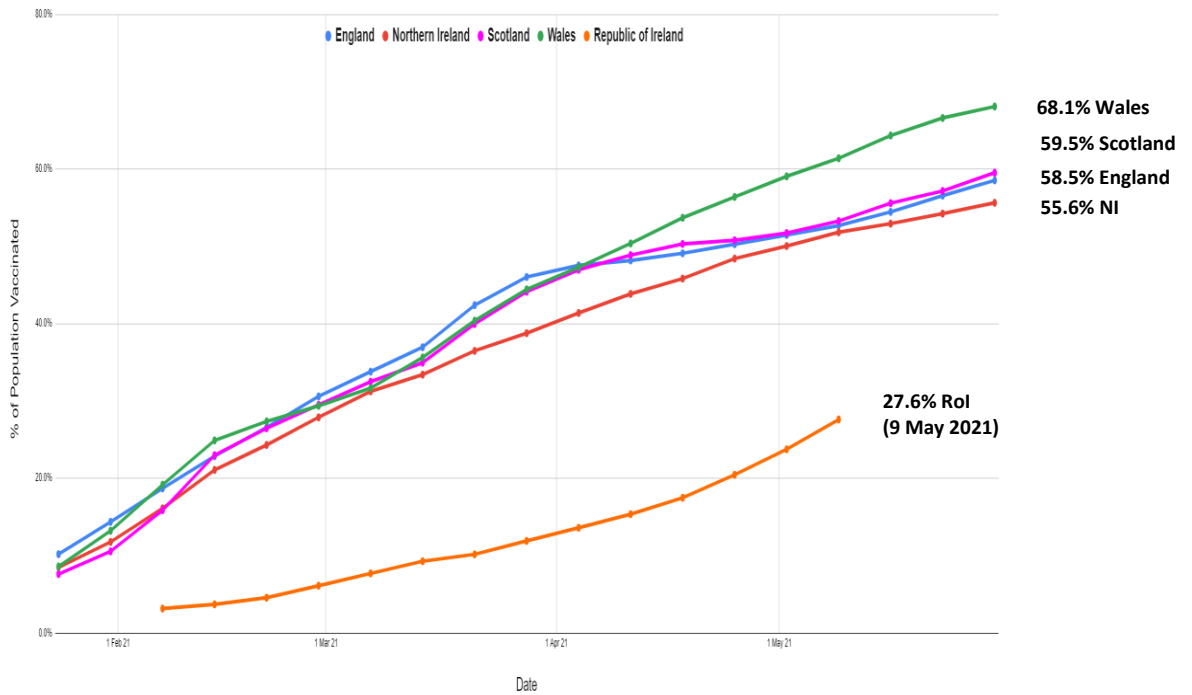
¹⁴⁶ Under the original vaccine allocation strategy this cohort was 'people aged 16-64 living or working in crowded settings, and in parallel, people aged 64 years and younger' but was changed following the introduction to an age-based system. There is no additional information on other cohorts at present, however, it should be noted that those in the 45-49 age bracket have commenced registration.

APPENDIX E

RATES OF COVID-19 VACCINATION IN THE UK AND IRELAND

(AS AT 1 JUNE 2021)

% of Population to Receive First Dose Vaccination



% of Population to Receive Second Dose Vaccination

